**PRO resources**

**Use of PROs in trials**

* Retzer A, Aiyegbusi OL, Rowe A, Newsome PN, Douglas-Pugh J, Khan S, Mittal S, Wilson R, O'Connor D, Campbell L, Mitchell SA, Calvert M. **The value of patient-reported outcomes in early-phase clinical trials.** Nat Med. 2022 Jan;28(1):18-20. doi: 10.1038/s41591-021-01648-4.
* Aiyegbusi, O.L., Roydhouse, J., Rivera, S.C. et al. **Key considerations to reduce or address respondent burden in patient-reported outcome (PRO) data collection**. Nat Commun 13, 6026 (2022). <https://doi.org/10.1038/s41467-022-33826-4>
* Kluetz PG, Kanapuru B, Lemery S, Johnson LL, Fiero MH, Arscott K, et al. **Informing the Tolerability of Cancer Treatments Using Patient-Reported Outcome Measures: Summary of an FDA and Critical Path Institute Workshop.** Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2018;21(6):742-7. Epub 2018/06/19. doi: 10.1016/j.jval.2017.09.009.
* Liu L, Choi J, Musoro JZ, Sauerbrei W, Amdal CD, Alanya A, et al. **Single-arm studies involving patient-reported outcome data in oncology: a literature review on current practice.** The Lancet Oncology. 2023;24(5):e197-e206. doi: 10.1016/S1470-2045(23)00110-9
* Dueck AC, Mendoza TR, Mitchell SA, Reeve BB, Castro KM, Rogak LJ, et al. **Validity and Reliability of the US National Cancer Institute's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).** JAMA Oncol. 2015;1(8):1051-9. Epub 2015/08/14. doi: 10.1001/jamaoncol.2015.2639. PubMed PMID: 26270597; PubMed Central PMCID: PMCPMC4857599.
* Hughes SE, Haroon S, Subramanian A, McMullan C, Aiyegbusi OL, Turner GM, et al. **Development and validation of the symptom burden questionnaire for long covid (SBQ-LC): Rasch analysis**. BMJ (Clinical research ed). 2022;377:e070230. doi: 10.1136/bmj-2022-070230.

**Selection of PRO measures**

* ePROVIDE (Mapi Research Trust). Provides resources to facilitate the development of endpoint strategy or identification of the right outcomes for studies. <https://eprovide.mapi-trust.org/about/about-eprovide>
* COSMIN. A resource to help you select the most suitable outcome measurement instruments. <https://www.cosmin.nl/>
* PROTEUS Consortium. Provides resources to guide the use of patient-reported outcomes (PROs) in clinical care, including planning the assessment strategy, collecting the data, interpreting the results, and using the findings to inform patient care. <https://theproteusconsortium.org/proteus-practice/>
* ISOQOL. The mission of ISOQOL is to advance the science of quality of life (QOL) and related patient-centered outcomes (PCO) in health research, care, and policy <https://www.isoqol.org/resource-center/>

**Protocol guidance (SPIRIT-PRO)**

* Calvert M, Kyte D, Mercieca-Bebber R, et al. **Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension**. JAMA. 2018;319(5):483–494. doi:10.1001/jama.2017.21903
* Calvert M, King M, Mercieca-Bebber R, Aiyegbusi O, Kyte D, Slade A, et al. **SPIRIT-PRO Extension explanation and elaboration: guidelines for inclusion of patient-reported outcomes in protocols of clinical trials.** BMJ Open. 2021;11(6):e045105. doi: 10.1136/bmjopen-2020-045105.

**PRO analysis (SISAQOL)**

* <https://event.eortc.org/sisaqol/>
* Coens C, Pe M, Dueck AC, Sloan J, Basch E, Calvert M, et al. **International standards for the analysis of quality-of-life and patient-reported outcome endpoints in cancer randomised controlled trials: recommendations of the SISAQOL Consortium.** The Lancet Oncology. 2020;21(2):e83-e96. doi: https://doi.org/10.1016/S1470-2045(19)30790-9.

**PRO reporting guidance (CONSORT-PRO)**

* Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD, et al. **Reporting of Patient-Reported Outcomes in Randomized Trials: The CONSORT PRO Extension**. Jama. 2013;309(8):814-22. <https://jamanetwork.com/journals/jama/fullarticle/1656259>

**Ethical and equitable utilisation of PROs**

* Calvert MJ, Cruz Rivera S, Retzer A, Hughes SE, Campbell L, Molony-Oates B, et al. **Patient reported outcome assessment must be inclusive and equitable**. Nature Medicine. 2022. doi: 10.1038/s41591-022-01781-8.<https://doi.org/10.1038/s41591-022-01781-8>
* Cruz Rivera S, Aiyegbusi OL, Ives J, Draper H, Mercieca-Bebber R, Ells C, et al. Ethical **Considerations for the Inclusion of Patient-Reported Outcomes in Clinical Research: The PRO Ethics Guidelines.** Jama. 2022;327(19):1910-9. doi: 10.1001/jama.2022.6421
* Slade, A.L., Retzer, A., Ahmed, K. et al. **Systematic review of the use of translated patient-reported outcome measures in cancer trials**. Trials 22, 306 (2021). <https://doi.org/10.1186/s13063-021-05255-z>

**Tools for patient partners involved in the co-design of trials with PRO endpoints**

* Cruz Rivera S, Stephens R, Mercieca-Bebber R, Retzer A, Rutherford C, Price G, et al. **‘Give Us The Tools!’: development of knowledge transfer tools to support the involvement of patient partners in the development of clinical trial protocols with patient-reported outcomes (PROs), in accordance with SPIRIT-PRO Extension.** BMJ Open. 2021;11(6):e046450. doi: 10.1136/bmjopen-2020-046450.

\*Note-Important to signpost for use with patient partners to support co-design of research with patients

* <https://www.birmingham.ac.uk/prolearn>

**Regulatory guidance**

* FDA Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims, 2009 <https://www.fda.gov/media/77832/download>
* FDA Patient-Focused Drug Development (PFDD) Guidance Series for Enhancing the Incorporation of the Patient’s Voice in Medical Product Development and Regulatory Decision Making

<https://www.youtube.com/watch?v=kQbbuhKWpX0>

https://[www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical](https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical)

* Appendix 2 to the guideline on the evaluation of anticancer medicinal products in man The use of patient-reported outcome (PRO) measures in oncology studies, 2016 <https://www.ema.europa.eu/en/documents/other/appendix-2-guideline-evaluation-anticancer-medicinal-products-man_en.pdf>
* ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials, 2020 <https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical-principles_en.pdf>