Appendix 2 - Glossary

Administration of PRO questionnaire	Refers to providing a questionnaire. The PRO questionnaire(s) may be provided to the participant/patient by a nurse or research team member known as 'trial coordinator', 'research nurse' or 'site coordinator'. Alternatively, the questionnaire may be sent by post or electronically.
Analysis metric	How the PRO concepts/domains used to evaluate the intervention is going to be analysed (e.g. change from baseline, final value, time to event)
Consent form	A form signed by the participant/patient prior receiving a treatment to confirm he/she agrees to the procedure and is aware of the potential benefits and risks of taking part.
Core Outcome Set (COS)	Refers to the minimum recommendations of what should be measured and reported in clinical trials of a specific healthcare area.
Discontinuation/deviation	Refers to the situation in which a patient departs from the approved protocol's procedure (see protocol).
Health-related quality of life	Multidimensional concept that describes or characterises the effect of a disease or treatment on a number of domains that capture a patients' physical functioning, psychological impact and social functioning.
Hypothesis	An idea or explanation for something that is based on known facts but has not yet been proved.
Imputation analysis	Mathematical approach used to 'fill in' missing data with plausible values to analyse incomplete data. This method has the potential to solve missing data.
Instrument scaling	Refers to the scale used to measure patients' responses. For example strongly disagree, disagree, neither agree nor disagree, agree and strongly agree.
Instrument scoring	A number derived from a patient's response to items in a questionnaire.
Interpretation guidelines	Statement in which it is indicates how to decide on the meaning of the PRO data collected during the clinical trial.
Intervention	Refers to the drugs, medical devices, procedures, vaccines, and other products that can be the focus of the study of the clinical trial.

Lost to follow-up	Refers to the participants who at one point in time were actively participating in a clinical research trial, but have become lost (either by error in a computer tracking system or by being unreachable) at the point of follow-up in the trial. They may drop out of a study because they have moved away, become ill, are unable to communicate or have died.[1]
Measurement properties	Criteria by which you can assess how good the questionnaire is. Some properties include 'reliability, validity and responsiveness' (see below).
Missing data	Situation in which participants fail to complete one or more components of an evaluation, fail to attend an evaluation, or are unavailable for the evaluation because of illness, death or other events such as moving house or holidays. Missing data is a problem for the trial as you have less information to analyse than planned.[1]
Mode(s) of PRO administration	Refers to the different ways a PRO questionnaire can be answered by a patient such as on paper or electronic.
Monitor of PRO data	Refers to the checking of questionnaire responses either to check for missing data and in some instances to inform the clinical care of trial participants.
Multiplicity or multiple testing	The more comparisons or multiple tests (e.g. analysis of multiple outcomes and comparisons across multiple treatment arms) are made, there is more chance of thinking that some real effects is present in the data when, in fact, none exists.
PRO objective	Provides the justification and purpose of assessing PROs in a clinical trial.
Participant information sheet	Document that provides potential participants information on the reason for the trial, any procedures that they might have to do (such as blood tests, PROs) and detailed information of the study to allow them to decide whether to take part and give informed consent.
Power of the principal PRO analyses	The number of patients required in order to detect a difference between PRO analyses.
PPI	PPI (patient and public involvement) refers to the research carried out 'with' or 'by' members of the public.[2]
Primary endpoint	The main result to see if a given treatment in a trial worked.[3]

PRO concepts	The PRO concept is a specific measurement goal (i.e., the thing that is to be measured by a PRO instrument).[4]
PRO domains	A PRO domain is a meaningful sub-set of a PRO measure such as emotional well-being or physical function.[4]
PRO-alerts	PRO data “concerning levels of psychological distress or physical symptoms that may require an immediate response".[5]
Protocol	Document that describes the objective(s), design, methodology and statistical considerations to conduct a specific clinical trial.
Proxy-reported outcome	Refers to those individuals (carer or family member) who answer a PRO questionnaire on behalf of the patient or trial participant.
Randomisation	An experimental study design in which participants are allocated by a random process to two or more study groups.
Recruitment target	The number of patients or trial participants that need to be enrolled in the clinical trial to meet protocol requirements.
Sensitivity analysis	Allows researchers and policy makers to assess how uncertainty in the results of the mathematical calculation is affected by different source of uncertainty. For example, if there is missing PRO data how much does this influence the results on whether a treatment worked.
Time windows	Specific period of time in which PRO data will be collected.
Type I error	The incorrect conclusion that two treatments differ, when in reality they do not.[1]
Validity	It is the degree to which an assessment measures what it is supposed to measure.[6]

1. Mayo N. Dictionary of Quality of Life and Health Outcomes Measurement. First ed: ISOQOL 2015.
2. INVOLVE. What is public involvement in research? : NIHR; [Available from: https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/ accessed May 2020.
3. National Cancer Institute - Dictionary of Cancer Terms [Available from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/primary-endpoint accessed November 2019.
4. US Food and Drug Administration. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims 2009 [accessed Dec 1 2017.
5. Kyte D, Ives J, Draper H, et al. Management of Patient-Reported Outcome (PRO) Alerts in Clinical Trials: A Cross Sectional Survey. *PLoS One* 2016;11(1):e0144658-e58. doi: 10.1371/journal.pone.0144658
6. Centre for Disease Control and Prevention: Health-Related Quality of Life (HRQOL) - Measurement Properties: Validity, Reliability, and Responsiveness 2018 [Available from: https://www.cdc.gov/hrqol/measurement.htm accessed Nov 2019.