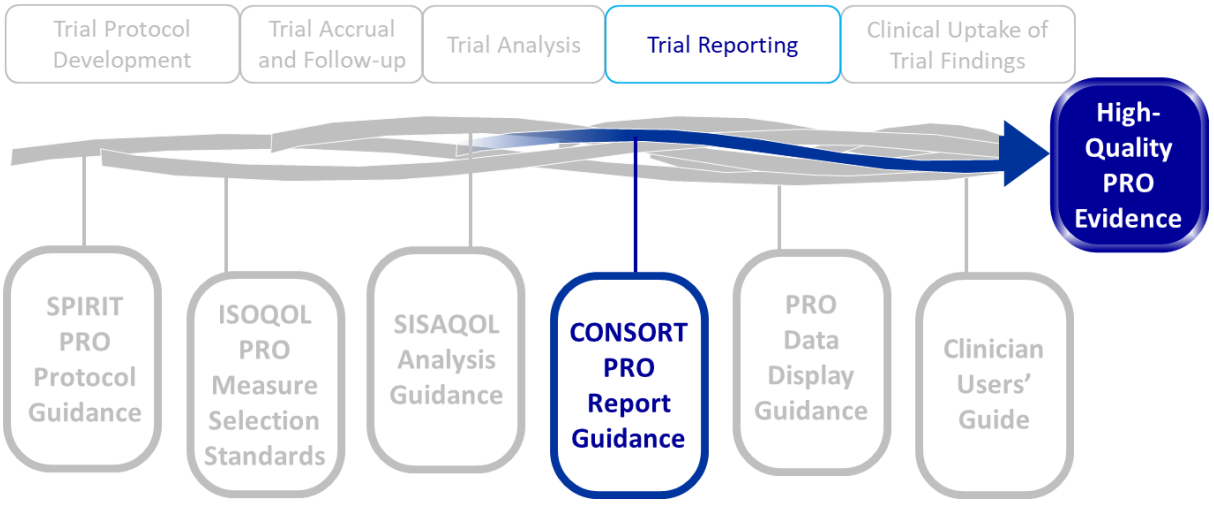
Chapter 5. Reporting PRO Findings

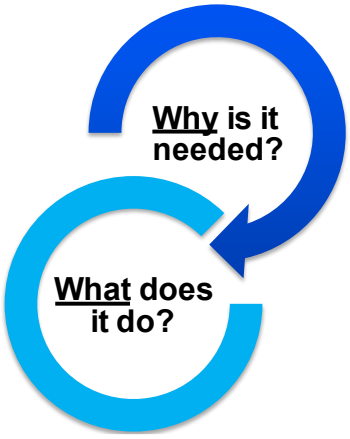


Consolidated Standards of Reporting Trials PRO Extension (CONSORT PRO)

The CONSORT guidance (Consolidated Standards of Reporting Trials) provides recommendations for publications reporting clinical trial results (Schulz et al., 2010). In 2013, a PRO-specific extension was published that addresses the specific elements related to PRO endpoints that should be included in clinical trial publications.

This chapter summarizes the recommendations for reporting PRO components of research studies.

Why is This Resource Needed?



To ensure that the PRO methods and results are clearly described in clinical trial publications

Identifies the relevant information to include in clinical trial publications with PRO endpoints

CONSORT PRO Summary of Reporting Guidance

The CONSORT PRO guidance constitutes an extension to the CONSORT statement that guides the reporting of clinical trials in general. The key items relevant to the reporting of PROs include the following:

Abstract

- Identify PRO as primary or secondary outcome

Background

- State PRO hypothesis, specifying domains, if applicable

Methods

- Provide/cite evidence of PRO instrument validity and reliability
- Summarize study procedures for PRO data collection
- State statistical approaches for dealing with missing PRO data

Discussion

- Address PRO-specific limitations and implications for generalizability in clinical practice

Why We Need PRO Reporting Guidance

- Clinicians, patients, and policy makers value PRO information
- Existing reporting guidelines are not adhered to
- Poor reporting hampers the use of PRO data in clinical practice and undermines the clinicians' ability to use PRO data in their practice to benefit patients

- Improved reporting of PRO data should facilitate robust interpretation of the results from clinical trials and inform patient care

Objective of Resource

The CONSORT (Consolidated Standards of Reporting Trials) Statement aims to improve the reporting of randomized controlled trials, but lacks guidance on the reporting of PROs. CONSORT PRO provides evidence-based extensions to the CONSORT statement for reporting PROs in clinical trials and elaborations on the CONSORT 2010 statements specifically as applied to PROs.

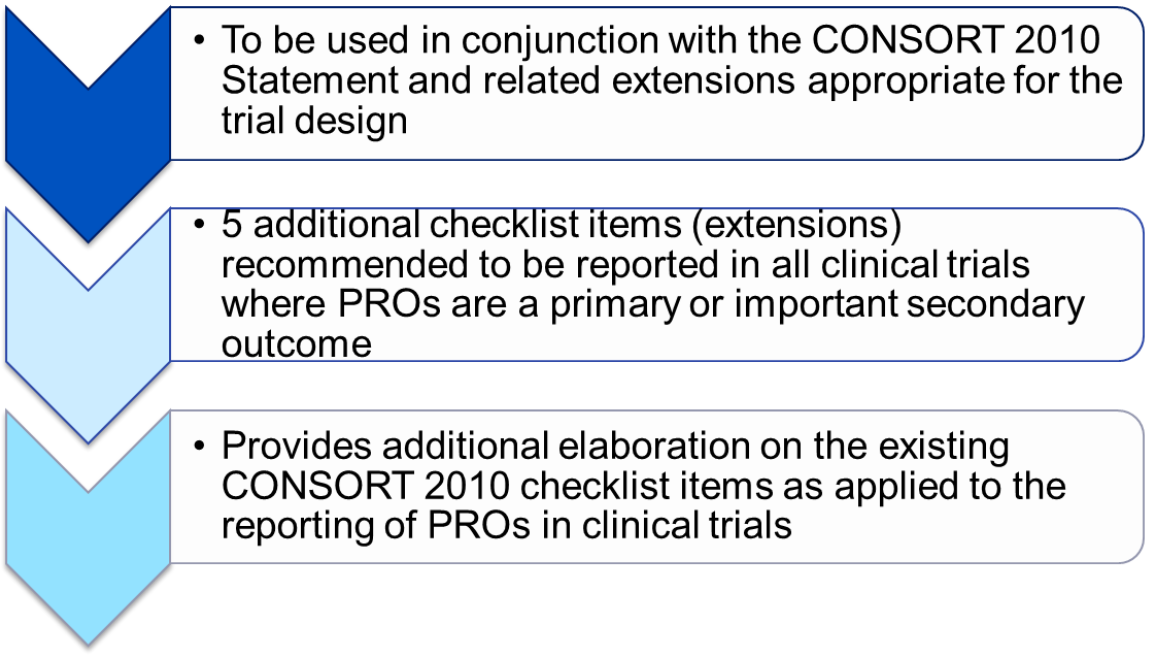
It is recommended that PRO data be presented in the primary clinical trial publication, as this will help ensure PROs are considered alongside other clinical outcomes.

Methods for Resource Development

The below figure illustrates the development process for the CONSORT PRO Guidance.

CONSORT PRO Reporting Guidance

Overview



CONSORT PRO Extensions and Elaborations

The CONSORT PRO Reporting Guidance identifies 5 additional items (extensions) to be reported in all RCTs in which PROs are a primary or important secondary outcome. An extension was deemed unnecessary for six existing CONSORT checklist items and therefore were elaborated for PRO endpoints. Below is a list of the CONSORT 2010 item and the corresponding PRO Extension and Elaborations 2013 item with a brief explanation. Please see Calvert et al. (2013) for the full explanation and real-world examples.

Abstract Item 1b

CONSORT 2010:	**PRO Extension 2013:**
Structured summary of trial design, methods, results, and conclusions.	The PRO should be identified in the abstract as a primary or secondary outcome.

Explanation:

Identifying the PRO as a primary or secondary outcome in the abstract will facilitate indexing and identification of studies to inform clinical care and evidence synthesis.

Introduction Item 2a

CONSORT 2010:	PRO Elaboration 2013:
Scientific background and explanation of rationale.	The relevant background and rationale for why PROs were assessed in the clinical trial should be briefly described.

Explanation:

The Background or Methods section should provide the rationale for including PROs and why the specific outcomes were selected, thus providing appropriate context for the PRO-specific objectives and hypotheses.

Introduction Item 2b

CONSORT 2010:	PRO Extension 2013:
Specific objectives or hypotheses.	The PRO hypothesis should be stated and relevant domains identified, if applicable.

Explanation:

Without a prespecified hypothesis there is risk of multiple statistical testing and selective reporting of significant results.

Methods Item 6a Extension

CONSORT 2010:	PRO Extension 2013:
Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed.	Evidence of PRO instrument validity and reliability should be provided or cited, if available.

Explanation:

Clinical use of PRO data requires that the trial results are robust, which depends on a valid and reliable PRO measure being used appropriately.

Methods Item 6a Elaboration

CONSORT 2010:

Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed.

PRO Elaboration 2013:

Details of the mode of PRO completion (in particular if a proxy completed the questionnaire on behalf of the patient), and the method of data collection (paper, telephone, electronic, other) should also ideally be provided particularly when the PRO is the primary outcome.

Explanation:

Different methods of data collection may affect the results and lead to potential bias if used differentially between intervention groups.

Methods Item 12a

CONSORT 2010:

Statistical methods used to compare groups for primary and secondary outcomes.

PRO Extension 2013:

Statistical approaches for dealing with missing data should be explicitly stated.

Explanation:

The level of missing PRO data is often high and can lead to reduced power, is a potential source of bias, and can result in misleading results.

Results Item 13a

CONSORT 2010:

For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome.

PRO Elaboration 2013:

The number of participants reporting PRO data at baseline and at subsequent time points should be made transparent.

Explanation:

The flow of participants through the trial in relation to PROs, including information on the reason for missing PRO data, should be reported to help readers interpret the PRO results and assess potential for bias.

Results Item 15

CONSORT 2010:	PRO Elaboration 2013:
Table showing baseline demographic and clinical characteristics for each group.	Including baseline PRO data when collected.

Explanation:

Baseline PRO data may be used by clinicians and policy makers to assess the relevance and generalizability of trial findings.

Results Item 17a

CONSORT 2010:	PRO Elaboration 2013:
For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval).	For multidimensional PROs, results from each domain and time point specified for analysis.

Explanation:

The potential for selective reporting of PROs is increased because study measures often contain multiple scales and items. In general, all PRO results should be presented alongside other outcome data to facilitate the clinical integration of the important findings with other prespecified outcomes.

Discussion Items 20/21

CONSORT 2010:	PRO Extension 2013:
Item 20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses. Item 21. Generalizability (external validity, applicability) of the trial findings.	PRO specific limitations and implications for generalizability of study findings and clinical practice.

Explanation:

Readers need to be able to assess generalizability and any potential sources of bias.

Discussion Item 22

CONSORT 2010:	PRO Elaboration 2013:
Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	PRO data should be interpreted in relation to clinical outcomes including survival data, where relevant.

Explanation:

The clinical significance of PRO results is often not discussed in clinical trial reports but should be interpreted in relation to other important clinical outcomes such as survival, especially in trials for which there are clinically relevant trade-offs between PROs and survival outcomes.

Implications of Using CONSORT PRO Guidance

- Improved PRO reporting in clinical trials will enable robust evidence to inform patient choice, aid clinical decision making, and inform health policy
- Active implementation by journals, authors, and reviewers may lead to improved reporting
- Endorse CONSORT PRO and other reporting guidelines
- PRO reporting is intrinsically linked to study design. Consider design in relation to:
    - FDA Guidance on PROs
    - SPIRIT Initiative

Checklist for the CONSORT PRO Reporting Guidance

Section/Topic	CONSORT-PRO Item	Recommended Content	Page Addressed
Title and Abstract			
	P1b	The PRO should be identified in the abstract as a primary or secondary outcome.	
Introduction			
Background and objectives	2a	The scientific background and explanation of rationale of PRO assessment should be included.	
	P2b	The PRO hypothesis should be stated, and relevant domains identified, if applicable.	
Methods			
Participants	4a	PRO-specific criteria are required only if PROs were used for eligibility or stratification.	
Outcomes	P6a	Evidence of PRO instrument validity and reliability should be provided or cited, including the person completing the PRO & methods of data collection (paper, telephone, or electronic).	
Sample size	7a	Sample size determination is required only if PRO is a primary study outcome.	
Randomization			
Statistical methods	P12a	Statistical approaches for dealing with missing data are explicitly stated.	
Results			
Participant flow	13a	The number of PRO outcome data at baseline and at subsequent time points should be transparent.	
Baseline data	15	PRO data in the table showing baseline demographic and clinical characteristics for each group should be included.	
Numbers analyzed	16	For each group, the number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups) is required for PRO results.	
Outcomes and estimation	17a	The estimated effect size and its precision such as 95% confidence interval should be presented for multidimensional PROs from each domain and time point.	
Ancillary analyses	18	Results of any other PRO analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory, should be presented if relevant.	
Discussion			
Limitations	P20/21	PRO-specific limitations and implications for generalizability and clinical practice should be presented.	
Interpretation	22	PRO data should be interpreted in relation to clinical outcomes including survival data if relevant.	

References

Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD, CONSORT PRO Group. Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. *JAMA*. 2013;309:814-822.

Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c332. doi:10.1136/bmj.c332

Further Reading

Brundage M, Bass B, Davidson J et al. Patterns of reporting health-related quality of life outcomes in randomized clinical trials: implications for clinicians and quality of life researchers. *Qual Life Res*. 2011; 20(5): 653-664.

Brundage M, Blazeby J, Revicki D et al. Patient Reported Outcomes in Randomized Clinical Trials: Development of ISOQOL Reporting Standards. *Qual Life Res* 2012; 22(6): 1161-75.

Calvert M, Kyte D, Mercieca-Bebber R, et al, for the SPIRIT-PRO Group. Guidelines for inclusion of Patient-Reported Outcomes in Clinical Trial Protocols The SPIRIT-PRO Extension. *JAMA* 2018;319(5):483-494.

Moher D, Hopewell S, Schulz KF et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010; 340:c869.

Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010; 340:c332.

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Please Note: When referencing information included in this Chapter, we recommend citing the primary sources rather than this Handbook.