



Improving patient involvement in cancer clinical trials: Development of plain language checklists within the SISAQOL-IMI initiative

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INTRODUCTION

- Improving the standardisation and transparency of patient-reported outcome (PRO) analysis in cancer trials is essential to support patient-centred treatment, care and shared decision-making.
- Cancer clinical trials involve multiple stakeholders who use varying methods to collect and analyse PRO data. This variation can make it difficult for decision makers to easily and fairly compare the results of cancer trials.
- The SISAQOL-IMI (Setting International Standards in Analysing Patient-Reported Outcomes and Quality of Life Endpoints – Innovative Medicines Initiative) aimed to establish consensus guidance for the design, analysis, presentation, and interpretation of health-related quality of life (HRQoL) data in oncology.

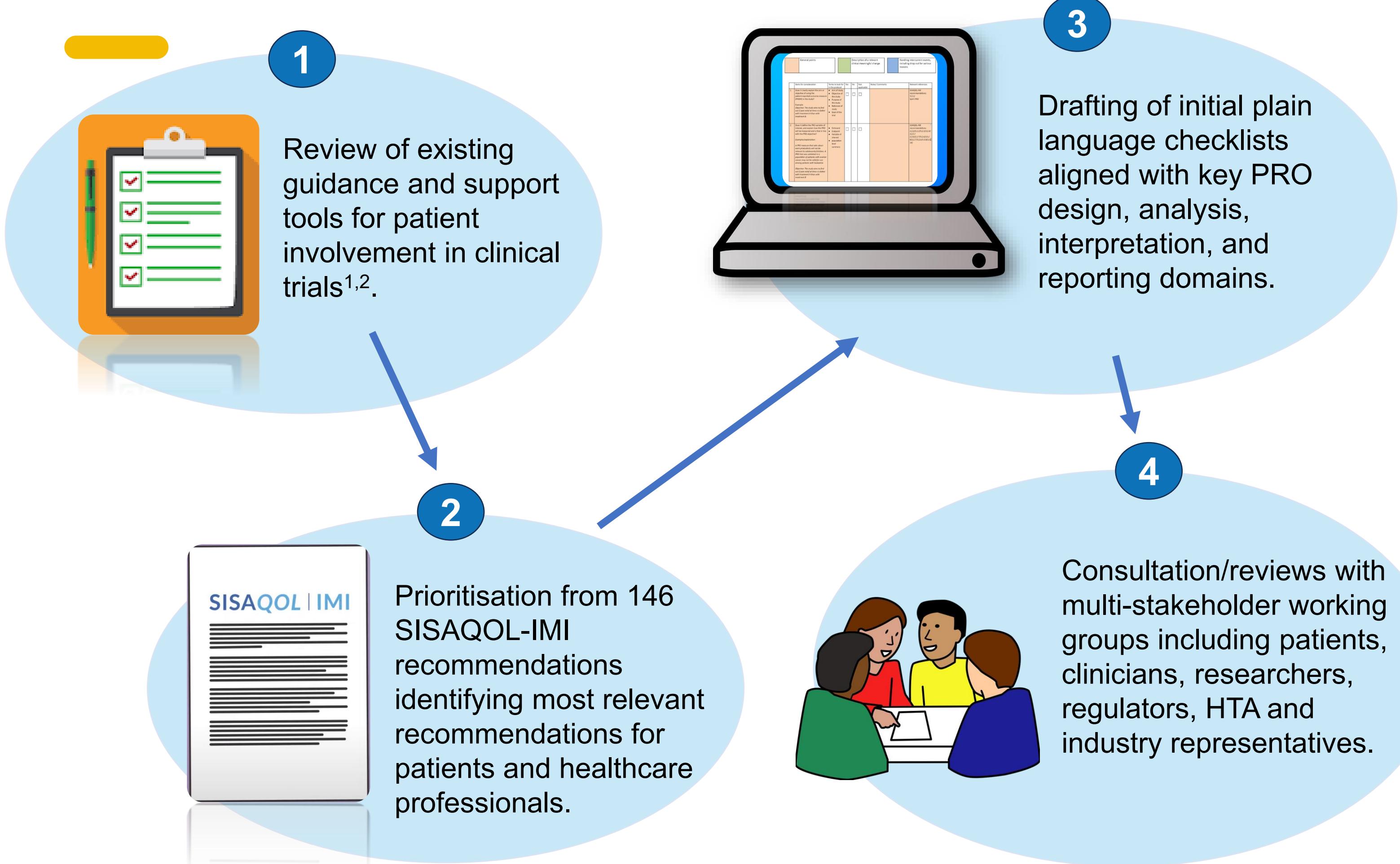
OBJECTIVE

A core component of the SISAQOL-IMI initiative was the development of plain language checklists to enhance patient involvement in the design of clinical trial protocols as well as to support patient advocates and healthcare professionals in providing feedback on clinical trial HRQoL results.

The main aims were to:

- Incorporate complex recommendations into a plain language version
- Design a supportive checklist with references and feedback/ notes tab

METHOD



RESULTS

Three plain language checklists were developed to support patients and healthcare professionals when reviewing cancer clinical trial protocols and cancer clinical trial results. Stakeholders valued consistent language, contextual interpretation, and visual aids.

Review of cancer clinical trial protocols

This checklist encompasses key domains including general points on PRO-related rationale, objectives, and endpoints (4 items); evaluation of validity (2 items), and PRO time points (2 items); PRO score interpretation thresholds (2 items); and strategies for handling intercurrent events (6 items).

General points		Description of a relevant PRO score interpretation threshold		Strategy for handling intercurrent events, including drop out for various reasons	
Items for consideration		Terms to search for in the protocol		Notes/Comments	
3 Does the protocol explain how the PRO will be measured?		<input type="checkbox"/> Questionnaire <input type="checkbox"/> Measure <input type="checkbox"/> PROM <input type="checkbox"/> Assessment <input type="checkbox"/> Variable of interest <input type="checkbox"/> Time point		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A Notes/Comments: SISAQOL-IMI recommendations (EstFrame1_GEN, Pop1_RCT, Pop2_RCT, EstFrame3_SAT, EstFrame4_SAT, EstFrame5_SAT, EstFrame6_SAT, Pop3_SAT, AnalMain9_SAT, PROvar2_RCT)	
4 Is the chosen PRO in line with the PRO objective?		<input type="checkbox"/> Endpoint <input type="checkbox"/> Variable of interest <input type="checkbox"/> Population-level summary		<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A Notes/Comments: SISAQOL-IMI recommendations (EstFrame1_GEN, Pop1_RCT, Pop2_RCT, EstFrame3_SAT, EstFrame4_SAT, EstFrame5_SAT, EstFrame6_SAT, Pop3_SAT, AnalMain9_SAT, PROvar2_RCT)	

Questions to think about when reviewing the protocol/ questions to ask the researchers about

Dropdown of examples/explanations for each question

3 colour coded sections focusing on different areas

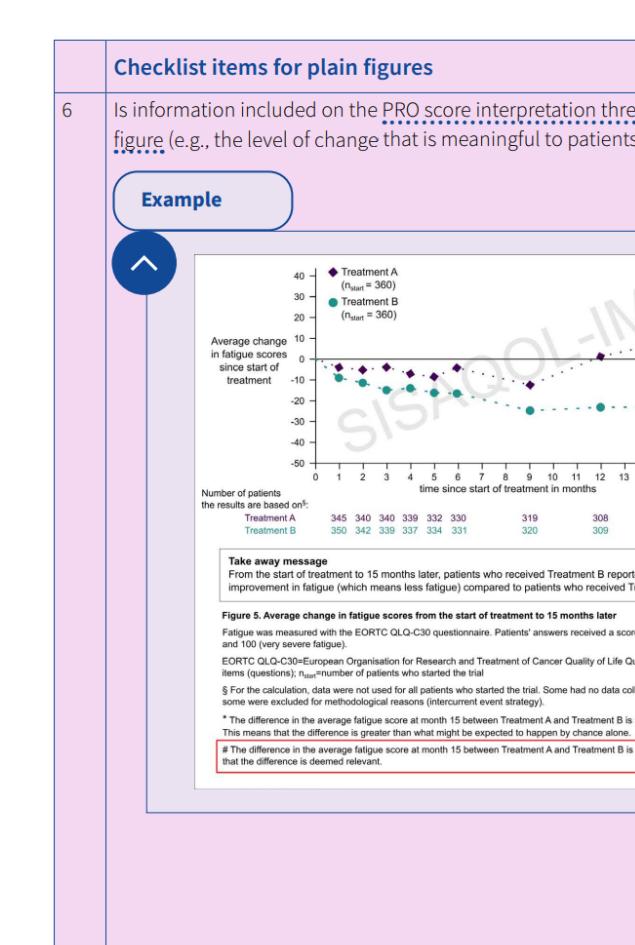
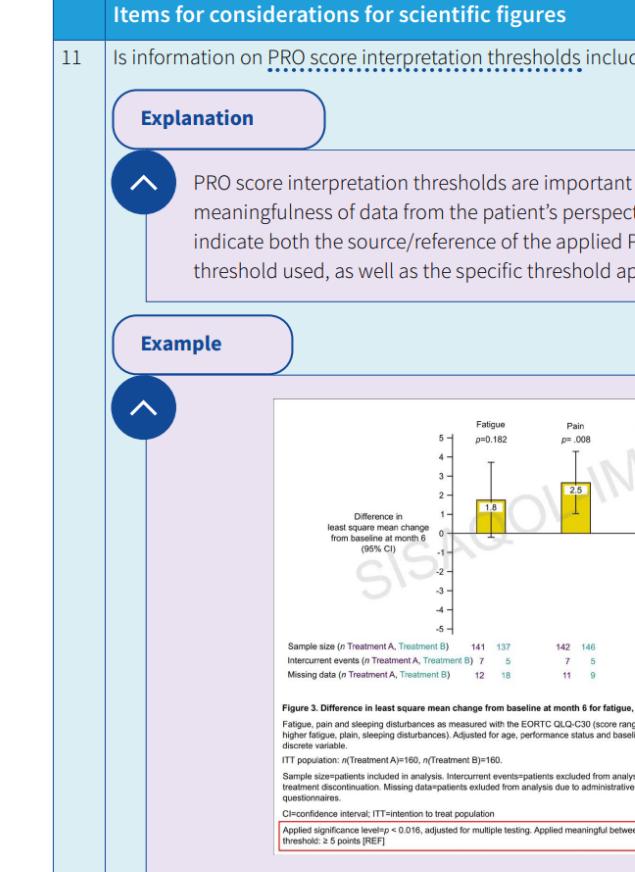
Terms that may be relevant to find the information in the protocol

Checkbox options to indicate whether questions were addressed and space to add notes

Reference to relevant SISAQOL-IMI recommendations

Review of scientific and plain language visualisations

These 2 checklists were developed to support the review of scientific visualisations (e.g. in publications) (11 items), and plain language visualisations (e.g. in plain language summaries) (6 items). Key items cover the reporting of missing data and handling of intercurrent events within visualisations and are supported with examples of best-practice graphs.

Checklist items for plain figures		Items for considerations for scientific figures	
6 Is information included on the PRO score interpretation threshold in the figure (e.g., the level of change that is meaningful to patients)?		11 PRO score interpretation thresholds are important to interpret the clinical meaning of data from the patient's perspective. Researchers should indicate both the source/reference of the applied PRO score interpretation threshold used, as well as the specific threshold applied.	
Example 		Example 	
Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> Notes/Comments: SISAQOL-IMI recommendations (Visc8_GEN)		Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/> Notes/Comments: SISAQOL-IMI recommendations (Visc1_GEN)	

Example template graphs

Red marker pointing to the relevant section of the graph.

Glossary terms

The checklists include 35 plain language definitions as a hover feature to provide a better overview/understanding of the items.

Translations

The checklists will be translated into 8 languages: French, German, Spanish, Japanese, Polish, Mandarin, Hindu, Italian.

CONCLUSIONS

The SISAQOL-IMI plain language checklists offer a co-produced, evidence-informed resource to better support stakeholders, including patient advocates, in the design of clinical trial protocols and promote meaningful and consistent interpretation of cancer PRO findings. Integrating these tools within the broader implementation of the SISAQOL-IMI recommendations will ultimately support patient-centric decision-making in oncology.

REFERENCES

¹ 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(8):814-822.

² Calvert M, Kyte D, Mercieca-Bebber R, Slade A, Chan A-W, King MT; and 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.



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