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

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On behalf of the SISAQOL-IMI Consortium

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.

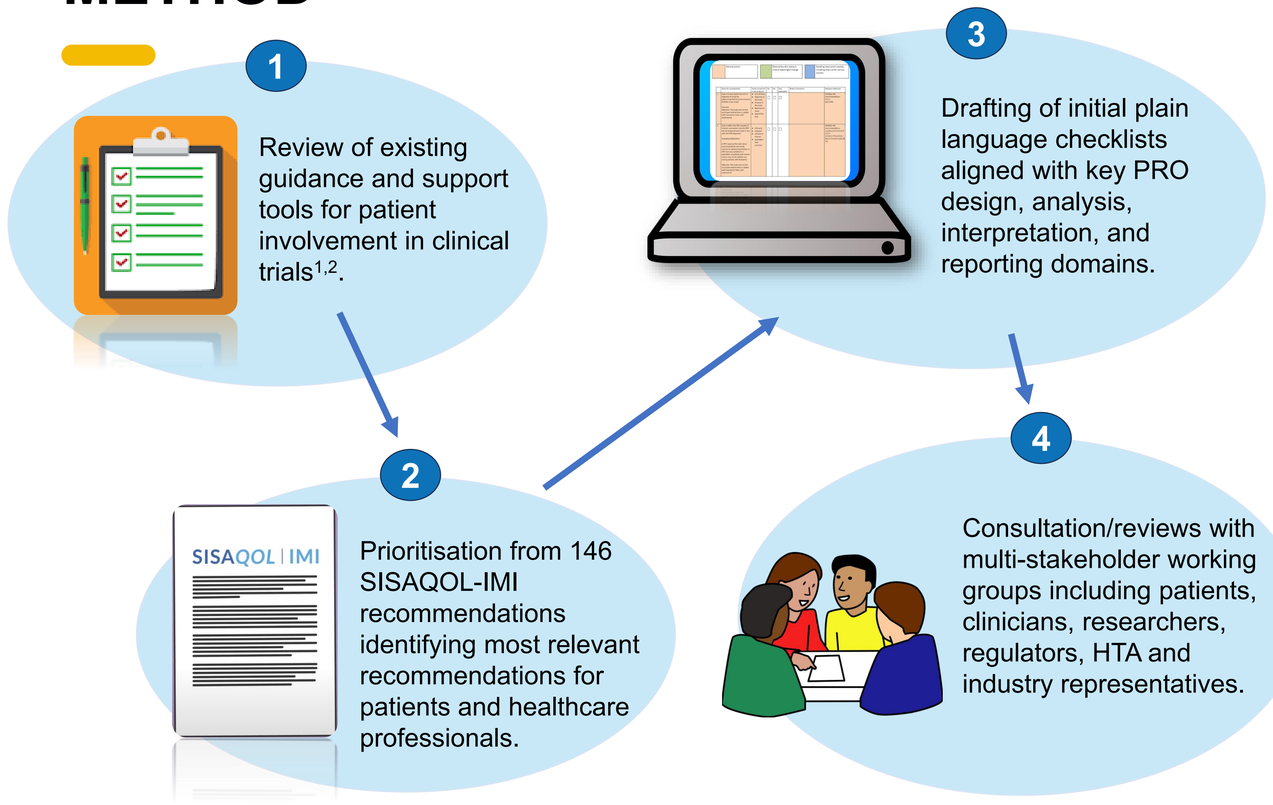
OBJECTIVE

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

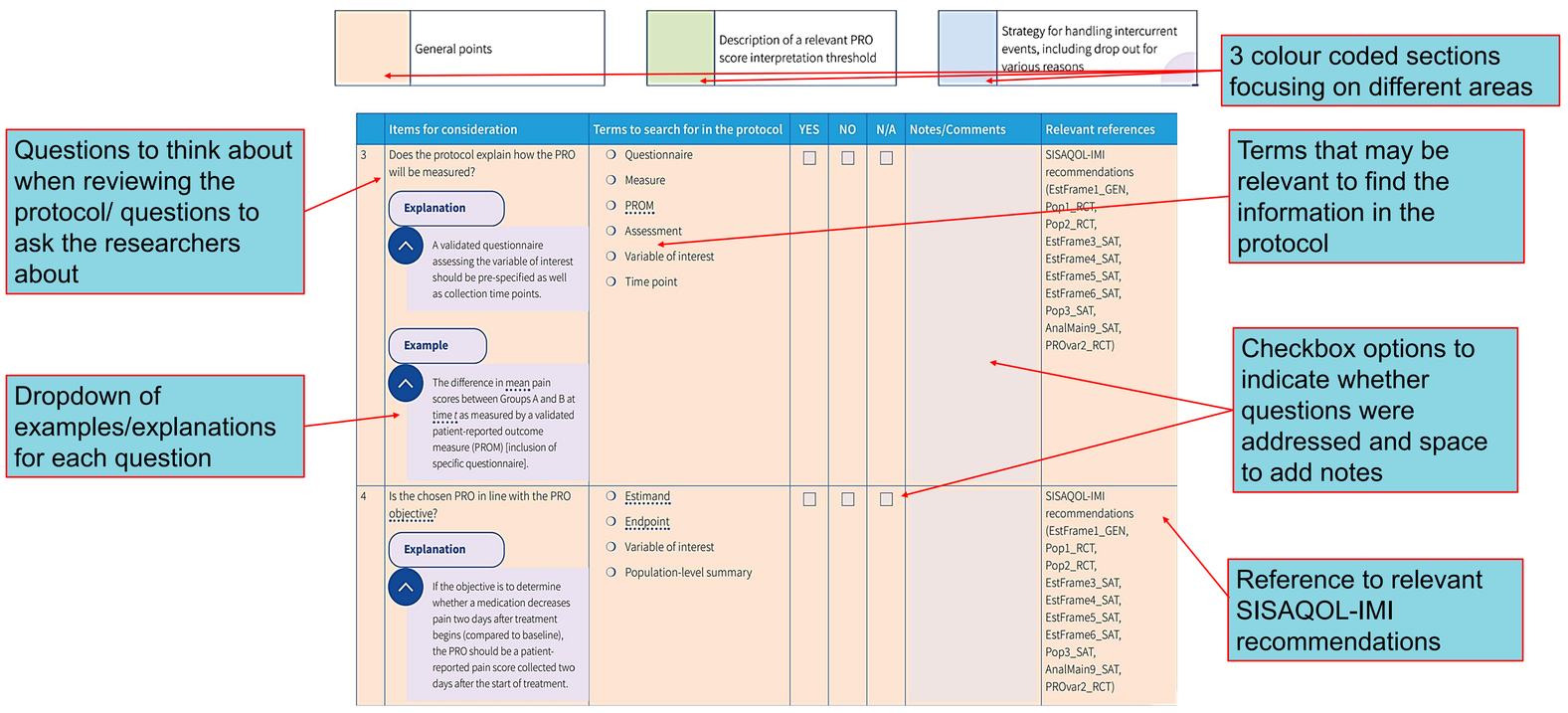


RESULTS

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.

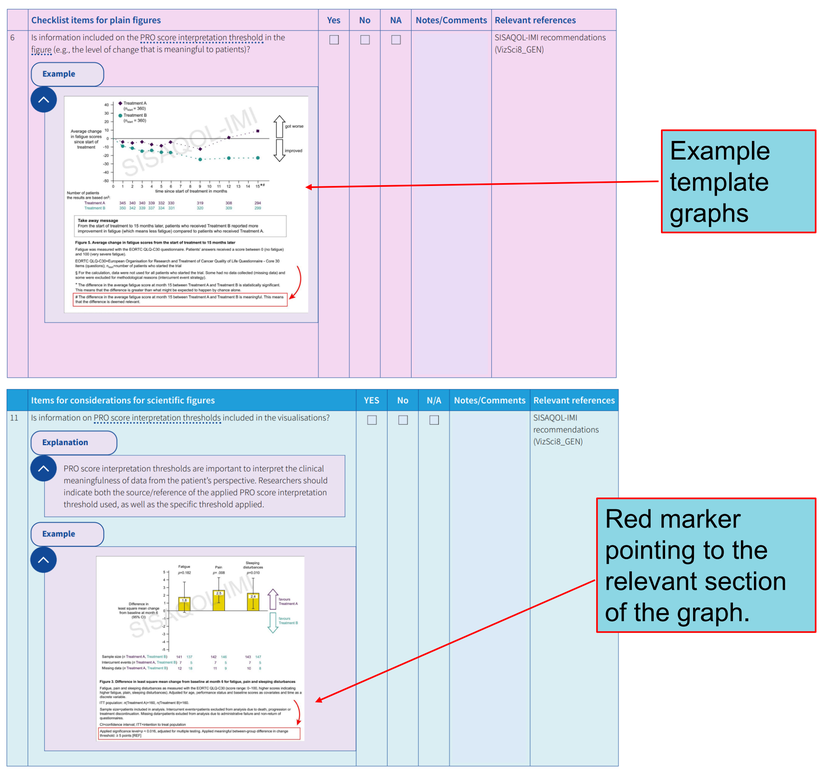
Review of cancer clinical trial protocols

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).



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.



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

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