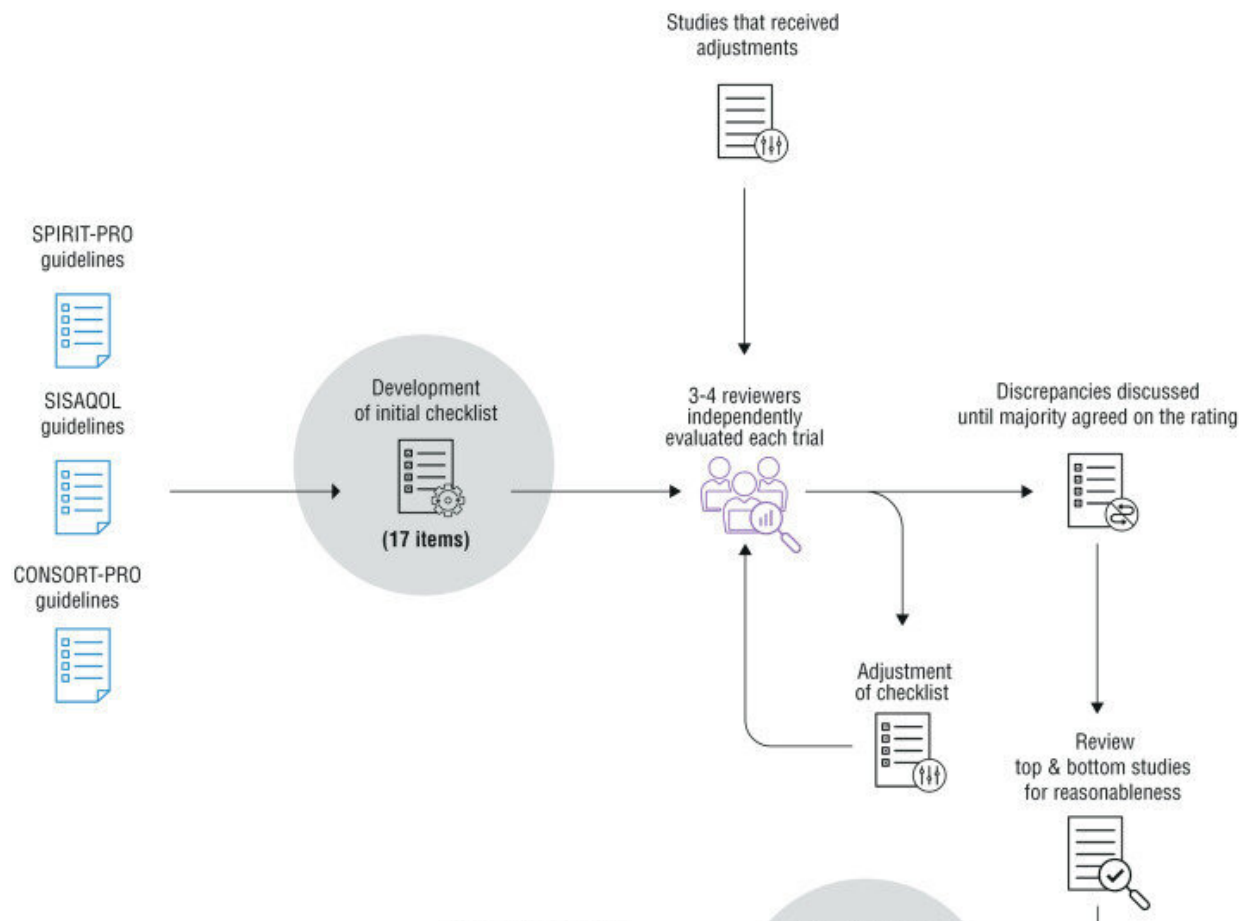


Novel checklist for 'quality of life' to take cancer clinical trials to the next level

December 20 2022



Credit: *Annals of Oncology* (2022). DOI: 10.1016/j.annonc.2022.12.004

The European Society for Medical Oncology (ESMO) has developed a quality of life (QoL) checklist that is now integral to the ESMO-

Magnitude of Clinical Benefit Scale (ESMO-MCBS)—a validated and reproducible tool to assess the magnitude of clinical benefit for cancer medicines.

The checklist, published today in *Annals of Oncology*, reflects the increasing importance of [quality of life](#) in the development of cancer therapies and aims to ensure QoL trial data meet specific standards, including reliability and validity, as part of ESMO-MCBS scoring.

"ESMO-MCBS is based on the concept that clinical benefits from a new treatment are not only to live longer, reflected by improved overall survival, but also to live better, reflected by improved QoL or reduced toxicity compared to the previous standard of care," explains lead author, Dr. Sjoukje Oosting, University Medical Center Groningen, The Netherlands, member of the ESMO-MCBS Extended Working Group.

She adds that QoL data can determine the final ESMO-MCBS score in several situations, citing the example of new treatments that are unlikely to be curative and where QoL is a primary or secondary endpoint. "Such treatments receive a preliminary ESMO-MCBS score based on overall or [progression-free survival](#), and gain a 1-point credit if global QoL is improved compared to the standard treatment arm."

Only QoL data that meets the standards defined in the checklist can be used for ESMO-MCBS scoring. "We hope and anticipate—says Dr. Oosting—that this checklist will promote methodologically better study design with regards to QoL and improve the quality of analysis and reporting. In this way, patients will be better informed about the impact of new treatment options."

In developing the QoL checklist, the ESMO-MCBS Working Group collaborated with the Quality of Life Department of the European Organisation for Research and Treatment of Cancer (EORTC).

Dr. Andrew Bottomley, Assistant Director—Head Quality of Life Department, EORTC, said, "This new addition to the ESMO-MCBS is a huge improvement to the scale and shows how important ESMO regards the patient view in cancer clinical trials. It was a privilege for the EORTC team to work with ESMO on updating this measure, and this shows the true value that academic societies like EORTC and ESMO place on the views of the patient".

Professor Nathan Isaac Cherny, Cancer Pain and Palliative Medicine Service, Department of Medical Oncology, Shaare Zedek Medical Center, Jerusalem, Israel, Chair of the ESMO-MCBS Working Group, explained the importance of ensuring QoL data are of a high standard.

"Quality of life is a complex construct and to measure it accurately we need to ensure that the proper tools are being used, that patients have been compliant in completing and returning data, and that when differences are claimed that they are not only statistically significant but also clinically meaningful."

Professor Cherny also explains the value of the checklist in drug development given that many cancer studies are based on progression-free survival, which as a surrogate outcome is not a reliable predictor of long-term outcomes.

"In the absence of a reliable predictor for living longer, you at least want to know 'will people live better?'. Only by adding in a quality of life outcome can you show that the treatment is improving quality of life or at least delaying deterioration of quality of life."

The [scoring system](#) is based on a short 4-item checklist: a clear hypothesis and methods of overall/global quality of life; compliance and missing data; results based on the hypothesis; and statistical and clinical significance.

"The importance of the [checklist](#) is that it ensures the data incorporated into the [ESMO-MCBS] score is valid and robust," says Cherny. "This is fundamental to facilitate objective and transparent decision-making on qualifying QoL studies for use in the ESMO-MCBS scoring." The authors add that to facilitate accurate QoL scoring, the ESMO-MCBS Working Group encourages timely reporting of all QoL results, including negative studies, according to existing guidelines for QoL research.

More information: S.F. Oosting et al, Methodological and reporting standards for quality of life data eligible for European Society for Medical Oncology-Magnitude of Clinical Benefit Scale (ESMO-MCBS) credit, *Annals of Oncology* (2022). [DOI: 10.1016/j.annonc.2022.12.004](https://doi.org/10.1016/j.annonc.2022.12.004)

Provided by European Society for Medical Oncology

Citation: Novel checklist for 'quality of life' to take cancer clinical trials to the next level (2022, December 20) retrieved 27 April 2024 from <https://medicalxpress.com/news/2022-12-checklist-quality-life-cancer-clinical.html>

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