ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

ESMO-MCBS QUALITY OF LIFE CHECKLIST

Based on the CONSORT-PRO, SPIRIT-PRO and SISAQOL recommendations

Name of study:					
Study medicine:		**Indication:**			
First author:		**Year:**		**Journal:**	
Name of evaluator:					

PREREQUISITES	Answer the below YES	NO
QoL was at least a secondary endpoint	○	○
Evidence of validity and reliability of used QoL instrument was provided, or cited if available	○	○
According to the conclusions, there was a statistically and clinically significant improvement in overall/global[a] QoL in comparison with the control arm[b]	○	○

a. For studies with QoL as primary endpoint, improvement in prespecified symptoms/domains can be credited.
b. For ESMO-MCBS form 3 (for single arm studies) this QoL checklist has not been validated.

If all three prerequisites are satisfied, please continue with the assessment below

Please note: If any of the three prerequisites are not satisfied, the evaluation cannot be continued and the upgrade for QoL cannot be claimed in the ESMO-MCBS score.

01. **Clear hypothesis and methods of overall/global[c] QoL including**	YES	NO
The timepoints of the QoL assessment	○	○
The direction of the expected change (for example, we expect a delay in the deterioration of overall/global QoL)	○	○

c. For studies with QoL as primary endpoint, improvement in prespecified symptoms/domains can be credited.

Item 1 result	YES	NO

Please note: If the answer to at least one of the above sub-items is "no", then the answer to item 1 will be "no"

CONSORT-PRO: Consolidated Standards of Reporting Trials on Patient Reported Outcomes; ESMO-MCBS: ESMO-Magnitude of Clinical Benefit Scale; QoL: Quality of Life; SISAQOL: Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data; SPIRIT-PRO: Standard Protocol Items Recommendations for Interventional Trials for Patient Reported Outcomes

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02. Compliance and missing data including

	YES	NO
High compliance rates (in your expert opinion) for each treatment arm and each time point (including baseline) reported	○	○
Statistical approach for dealing with missing data explicitly stated without ignoring the missing data	○	○
Item 2 result	YES	NO

Please note: If the answer to at least one of the above sub-items is "no", then the answer to item 2 will be "no"

If the answer to item 1 was "no", then item 3 is not applicable

03. Results (based on hypothesis) including

	N/A	YES	NO
Results from primary QoL analysis and time point(s) are reported with the estimated effect size and its precision (such as 95% confidence interval)		○	○
The results are based on the original assigned groups		○	○
Item 3 result	N/A	YES	NO

Please note: If the answer to at least one of the above sub-items is "no", then the answer to item 3 should be "no"

04. Statistical and clinical significance including

	YES	NO
Clear description of primary statistical method for the analysis	○	○
Correction for multiplicity if more than one follow-up assessment or instrument are used in the primary analysis	○	○
Pre-defined threshold for clinical relevance (i.e. minimal important difference)	○	○
Item 4 result	YES	NO

Please note: If the answer to at least one of the above sub-questions is "no", then the answer to item 4 should be "no"

Final number of items scored positively	/4

Please note that the positive fulfillment of at least two items are mandatory for a QoL adjustment in the ESMO-MCBS score until January 2025. For studies published after 1st January 2025, all four items are required to be positively fulfilled for a QoL adjustment in the ESMO-MCBS score.

ESMO-MCBS: ESMO-Magnitude of Clinical Benefit Scale; N/A: not applicable; QoL: Quality of Life.