

ESMO-MCBS QUALITY OF LIFE CHECKLIST

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

Name of study:	<input type="text"/>		
Study medicine:	<input type="text"/>	Indication:	<input type="text"/>
First author:	<input type="text"/>	Year:	<input type="text"/>
		Journal:	<input type="text"/>
Name of evaluator:	<input type="text"/>		

PREREQUISITES	Answer the below	
	YES	NO
QoL was at least a secondary endpoint	<input type="radio"/>	<input type="radio"/>
Evidence of validity and reliability of used QoL instrument was provided, or cited if available	<input type="radio"/>	<input type="radio"/>
According to the conclusions, there was a statistically and clinically significant improvement in overall/global ^a QoL in comparison with the control arm ^b	<input type="radio"/>	<input type="radio"/>

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	<input type="radio"/>	<input type="radio"/>
The direction of the expected change (for example, we expect a delay in the deterioration of overall/global QoL)	<input type="radio"/>	<input type="radio"/>

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

Item 1 result	<input type="radio"/>	<input type="radio"/>
----------------------	-----------------------	-----------------------

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"

02. Completion and missing data including

YES NO

High completion 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

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.