ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE

ESMO-MCBS AND ESMO-MCBS:H 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]	○	○

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[a] 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)	○	○

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"

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.

CONSORT-PRO: Consolidated Standards of Reporting Trials on Patient Reported Outcomes; ESMO-MCBS: ESMO-Magnitude of Clinical Benefit Scale; ESMO-MCBS:H: ESMO-Magnitude of Clinical Benefits Scale for Haematological Malignancies; 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

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

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