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

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 QoL in comparison with the control arm

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 QoL including

   a. The timepoints of the QoL assessment

   b. 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.

   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. **Compliance and missing data including**

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<th>YES</th>
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- 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**

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**

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- 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**

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**

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- 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**

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.