ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

EVALUATION FORM 2C - ESMO-MCBS v2.0

For therapies that are not likely to be curative with primary endpoint other than OS or PFS or non-inferiority studies

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

Primary outcome is response rate or quality of life OR non-inferiority studies

GRADE 4	Reduced toxicity or improved QoL (using the ESMO-MCBS QoL checklist) with evidence for statistical non-inferiority or superiority in PFS/OS	☐
GRADE 3	Improvement in some symptoms (using the ESMO-MCBS QoL checklist) BUT without evidence of improved overall QoL	☐
GRADE 2	RR is increased ≥20% (and no significant benefit in PFS or OS)	☐
GRADE 1	RR is increased <20% (and no significant benefit in PFS or OS)	☐

Mark with √ if relevant

Preliminary magnitude of clinical benefit score	**4** ☐	**3** ☐	**2** ☐	**1** ☐

ESMO-MCBS, European Society For Medical Oncology-Magnitude of Clinical Benefit Scale; OS, overal survival; PFS, progression-free survival; QoL, quality of life; RR, response rate.

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Incremental toxicity (for response rate studies only)

Is the new treatment associated with an incremental rate of:

- Fatal adverse events ≥2% of patients ☐
- Premature discontinuation of therapy in ≥10% of patients ☐
- Hospitalisation for adverse events in ≥10% of patients ☐
- Grade ≥3 mucositis in ≥10% of patients ☐
- Grade ≥3 diarrhoea in ≥10% of patients ☐
- Grade ≥3 fatigue in ≥10% of patients ☐
- Grade ≥3 neurotoxicity in ≥10% of patients ☐
- Other distressing toxicity grade ≥3 in ≥10% of patients ☐
- Overall grade 3-4 toxicity impacting on daily well-being* or serious adverse events in ≥20% of patients ☐

Note: Incremental rate refers to the comparison versus standard therapy in the control arm.

Mark with √ if relevant

*This does not include alopecia, myelosuppression, but rather chronic nausea, diarrhoea, fatigue, etc.

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Quality of life/Grade 3-4 toxicities assessment (for RR studies only)

Was QoL evaluated? ☐

Is QoL improved according to the ESMO-MCBS QoL checklist? ☐

Are there fewer grade 3-4 toxicities impacting on daily well-being*? ☐

*This does not include alopecia, myelosuppression, but rather chronic nausea, diarrhoea, fatigue, etc.

Mark with √ if relevant

Adjustements (for RR studies only)

01. When OS as secondary endpoint shows improvement, it will prevail and the scoring should be done according to form 2a

02. When PFS as secondary endpoint shows improvement, and there is no OS data, it will prevail and the scoring should be done according to form 2b.

03. Upgrade 1 level if study demonstrates:

a. Improved QoL using the ESMO-MCBS QoL checklist OR

b. Fewer grade 3-4 toxicities that affect well-being of patients

04. Downgrade 1 level if the treatment has incremental toxicity

Magnitude of clinical benefit score	**4** ☐	**3** ☐	**2** ☐	**1** ☐

Note: Highest magnitude clinical benefit grade that can be achieved in form 2c is grade 4 and the lowest is 1.

Non-curative setting grading 5 and 4 indicate a substantial magnitude of clinical benefit.

OS, overall survival; PFS, progression-free surival; QoL, Quality of Life; RR, response rate.