ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

Evaluation form 2b: For therapies that are not likely to be curative with primary endpoint PFS

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

IF median PFS with standard treatment >6 months

	Mark with √ if relevant
Grade 3	
HR ≤0.65 AND gain ≥3 months	
Grade 2	
HR ≤0.65 BUT gain <3 months	
Grade 1	
HR >0.65	

Preliminary magnitude of clinical benefit grade (highest grade scored)

3	2	1

HR, hazard ratio; PFS, progression-free survival.

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Toxicity assessment

Is the new treatment associated with a statistically significant incremental rate of:	Mark with √ if relevant
«Toxic» death >2%	
Cardiovascular Ischemia >2%	
Hospitalization for «toxicity» >10%	
Excess rate of severe CHF >4%	
Grade 3 neurotoxicity >10%	
Severe other irreversible or long lasting toxicity >2% please specify:	

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

Quality of Life/Grade 3-4 toxicities* assessment

	Mark with √ if relevant
Was QoL evaluated as secondary outcome?	
Does secondary endpoint QoL show improvement?	
Are there statistically significantly less grade 3-4 toxicities impacting on daily well-being*?	

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

Adjustments

a) Downgrade 1 level if there is one or more of the above incremental toxicities associated with the new medicine
b) Upgrade 1 level if improved QoL or if less grade 3-4 toxicities that bother patients are demonstrated
c) When OS as secondary endpoint shows improvement, it will prevail and the new scoring will be done according to form 2a
d) Downgrade 1 level if the medicine ONLY leads to improved PFS, QoL assessment does not demonstrate improvement

Final, toxicity adjusted, magnitude clinical benefit grade

4	3	2	1

Highest magnitude clinical benefit grade that can be achieved grade 4.

CHF, congestive heart failure; OS, overall survival; PFS, progression-free survival; QoL, Quality of Life.