

## ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 2B

For therapies that are not likely to be curative with primary endpoint PFS

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"/>		

If median PFS with standard treatment >6 months

<b>GRADE 3</b>	HR $\leq 0.65$ <u>AND</u> gain $\geq 3$ months	<input type="radio"/>
<b>GRADE 2</b>	HR $\leq 0.65$ <u>BUT</u> gain $< 3$ months	<input type="radio"/>
<b>GRADE 1</b>	HR $> 0.65$	<input type="radio"/>

Mark with  $\checkmark$  if relevant

<b>Preliminary magnitude of clinical benefit grade (highest grade scored)</b>	<b>3</b>	<b>2</b>	<b>1</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

## Early stopping or crossover

Did the study have an early stopping rule based on interim analysis of survival?

Was the randomization terminated early based on the detection of overall survival advantage at interim analysis?

If the answer to both is "yes", then see letter "E" in the adjustment section below

Mark with  if relevant

## Toxicity assessment

Is the new treatment associated with a statistically significant incremental rate of:

«Toxic» death >2%

Cardiovascular ischemia >2%

Hospitalisation for «toxicity» >10%

Excess rate of severe CHF >4%

Grade 3 neurotoxicity >10%

Severe other irreversible or long lasting toxicity >2% please specify:

(Incremental rate refers to the comparison versus standard therapy in the control arm)

Mark with  if relevant

## Quality of life/Grade 3-4 toxicities\* assessment

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.

Mark with  if relevant

# ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

## Adjustments

- A** When OS as secondary endpoint shows improvement, it will prevail and the new scoring will be done according to form 2a.
- B** Downgrade 1 level if there is one or more of the above incremental toxicities associated with the new medicine.
- C** Downgrade 1 level if the medicine ONLY leads to improved PFS (mature data shows no OS advantage) and QoL assessment does not demonstrate improved QoL.
- D** Upgrade 1 level if improved QoL or if less grade 3-4 toxicities that bother patients are demonstrated.
- E** Upgrade 1 level if study had early crossover because of early stopping or crossover based on detection of survival advantage at interim analysis.
- F** Upgrade 1 level if there is a long-term plateau in the PFS curve, and there is >10% improvement in PFS at 1 year.

<b>Final, toxicity and QoL adjusted, magnitude of clinical benefit grade</b>	<b>4</b> <input type="checkbox"/>	<b>3</b> <input type="checkbox"/>	<b>2</b> <input type="checkbox"/>	<b>1</b> <input type="checkbox"/>
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Highest magnitude clinic benefit grade that can be achieved grade 4.

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

PFS, progression-free survival; OS, overall survival; QoL, quality of life