

ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale
for Haematological Malignancies

EVALUATION FORM 2A

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

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 OS with the standard treatment is ≥ 12 - < 24 months

GRADE 4	HR ≤ 0.70 <u>AND</u> gain ≥ 5 months	<input type="radio"/>
	Increase in 3-year survival alone $\geq 10\%$ (if $> 20\%$ of patients have reached 3-year OS)	<input type="radio"/>
GRADE 3	HR ≤ 0.70 <u>AND</u> gain ≥ 3 - < 5 months	<input type="radio"/>
GRADE 2	HR ≤ 0.70 <u>AND</u> gain ≥ 1.5 - < 3 months	<input type="radio"/>
	HR > 0.70 - 0.75 <u>AND</u> gain ≥ 1.5 months	<input type="radio"/>
GRADE 1	HR > 0.75 <u>OR</u> gain < 1.5 months	<input type="radio"/>

Mark with \surd if relevant

Preliminary magnitude of clinical benefit score	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>
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Quality of Life/Grade 3-4 toxicities assessment

Was QoL evaluated as secondary outcome?

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

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

Adjustments

01. Upgrade 1 level if improved QoL and/or fewer grade 3-4 toxicities impacting daily well-being are shown
02. If there is a long-term plateau in the survival curve, and OS advantage continues to be observed at 5 years, also score according to form 1a (treatments with curative potential) and present both scores i.e. A/4

Final adjusted magnitude of clinical benefit score	5 <input type="checkbox"/>	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>
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Non-curative setting grading 5 and 4 indicate a substantial magnitude of clinical benefit