

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 ≥ 36 months or not reached with ≥ 36 months follow-up

GRADE 4	HR ≤ 0.70 <u>AND</u> gain ≥ 12 months	<input type="radio"/>
	HR ≤ 0.65 <u>AND</u> interim OS gain $\geq 20\%$ (if OS is not mature)	<input type="radio"/>
	Increase in 7-year survival alone $\geq 10\%$ (if $>20\%$ of patients have reached 7-year OS)	<input type="radio"/>
GRADE 3	HR ≤ 0.70 <u>AND</u> gain ≥ 8 - <12 months	<input type="radio"/>
	HR ≤ 0.65 <u>AND</u> interim OS gain 10-20% (if OS is not mature)	<input type="radio"/>
GRADE 2	HR ≤ 0.70 <u>AND</u> gain ≥ 6 - <8 months	<input type="radio"/>
	HR >0.70 - 0.75 <u>AND</u> gain ≥ 6 months	<input type="radio"/>
	HR ≤ 0.65 <u>AND</u> interim OS gain $<10\%$ (if OS is not mature)	<input type="radio"/>
GRADE 1	HR >0.75 <u>OR</u> gain <6 months	<input type="radio"/>

Mark with \checkmark if relevant

Preliminary magnitude of clinical benefit score	4 <input type="checkbox"/>	3 <input type="checkbox"/>	2 <input type="checkbox"/>	1 <input type="checkbox"/>
--	-----------------------------------	-----------------------------------	-----------------------------------	-----------------------------------

ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale
for Haematological Malignancies

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 10-year, 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"/>
---	-----------------------------------	-----------------------------------	-----------------------------------	-----------------------------------	-----------------------------------

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