

EVALUATION FORM 2A

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

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

If median OS with the standard treatment is <12 months

GRADE 4	HR ≤0.65 <u>AND</u> gain ≥3 months	
	Increase in 2-year survival $\ge 10\%$ (if $>20\%$ of patients have reached 2-year OS)	\bigcirc
GRADE 3	HR ≤0.65 <u>AND</u> gain ≥2 - <3 months	\bigcirc
GRADE 2	HR ≤0.65 <u>AND</u> gain ≥1.5 - <2 months	\bigcirc
	HR >0.65 - 0.70 <u>AND</u> gain ≥1.5 months	\bigcirc
GRADE 1	HR >0.70 <u>OR</u> gain <1.5 months	\bigcirc

Mark with $\sqrt{}$ if relevant

Preliminary magnitude of clinical benefit score	4	3	2	1



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?	\bigcirc
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 $\sqrt{}$ 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-year, <u>also score</u> according to form 1a (treatments with curative potential) and present both scores i.e. A/4



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