ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale
for Haematological Malignancies

EVALUATION FORM 3

For single arm studies in "orphan diseases" and for diseases with "high unmet need" when primary outcome is PFS or ORR

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

GRADE 3	PFS >6 months	☐
	ORR (PR+CR) ≥60%	☐
	ORR (PR+CR) ≥20 - <60% AND duration of response ≥9 months	☐
GRADE 2	PFS 3-6 months	☐
	ORR (PR+CR) ≥40 - <60%	☐
	ORR (PR+CR) ≥20 - <40% AND duration of response ≥6 - <9 months	☐
GRADE 1	PFS 2 - <3 months	☐
	ORR (PR+CR) ≥20 - <40%	☐
	ORR (PR+CR) >10 - <20% AND duration of response ≥6 months	☐

Mark with √ if relevant

Preliminary magnitude of clinical benefit score	**3** ☐	**2** ☐	**1** ☐

CR, complete remission; ORR, overall response rate; PFS, progression-free survival; PR, partial response.

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Quality of Life/Grade 3-4 toxicities assessment

Was QoL evaluated as secondary outcome?	☐
Does secondary endpoint QoL show improvement?	☐
Are there ≥30% 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. Downgrade 1 level if there are ≥30% grade 3-4 toxicities impacting on daily well-being*

02. Upgrade 1 level if improved QoL

03. Upgrade 1 level for confirmatory, adequately sized, phase 4 experience

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

Note: No more than 1 upgrade is possible

Final adjusted magnitude of clinical benefit score	4 ☐	3 ☐	2 ☐	1 ☐

Note: Highest magnitude clinical benefit grade that can be achieved in form 3 is grade 4

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

QoL, Quality of Life.