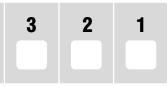


ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 3

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

Name of stu	dy:				
Study medicine:		Indication:	Indication:		
First author:		Year:	Journal:		
Name of eva	luator:				
GRADE 3	PFS ≥6 months				
	ORR (PR+CR) ≥60%				
	ORR (PR+CR) ≥20-<60	% <u>AND</u> DoR ≥9 months			
GRADE 2	PFS ≥3-<6 months		\bigcirc		
	ORR (PR+CR) ≥40-<60	%			
	ORR (PR+CR) ≥20-<40	% <u>AND</u> DoR ≥6-<9 months			
GRADE 1	PFS 2-<3 months		\bigcirc		
	ORR(PR+CR) ≥20-<409	% <u>AND</u> DoR <6 months			
	ORR (PR+CR) >10-<20% <u>AND</u> DoR ≥6 months				
			Mark with $$ if relevant		

Preliminary magnitude of clinical benefit grade (highest grade scored)



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



Quality of life/Grade 3-4 toxicities* assessment

Was QoL evaluated as secondary outcome?	
Does secondary endpoint QoL show improvement?	
Are there \geq 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 $\sqrt{}$ if relevant

Adjustments

- A Downgrade 1 level if there are ≥30% grade 3-4 toxicities impacting on daily well-being*
- B Upgrade 1 level if improved QoL
- **C** Upgrade 1 level for confirmatory, adequately sized, phase 4 experience

	4	3	2	1
Final adjusted magnitude of clinical benefit grade				

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

QoL, quality of life