ESMO Magnitude of Clinical Benefit Scale v1.1

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 drug:	**Indication:**		
First author:	**Year:**	**Journal:**	
Name of evaluator:			

Grade 3	Mark with X if relevant
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 months <9 months	

Grade 1

PFS 2-<3 months	
ORR (PR+CR) ≥20 <40% AND Duration of response <6 months	
ORR (PR+CR) >10 <20% AND Duration of response ≥6 months	

Preliminary magnitude of clinical benefit grade (highest grade scored)

3	2	1

Quality of life/ grade3-4 toxicities assessment

Was quality of life (QoL) evaluated as secondary outcome?	
Does secondary endpoint quality of life 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.**

Adjustments

a. **Downgrade 1 level if there are ≥30% grade 3-4 toxicities impacting on daily well-being***
b. **Upgrade 1 level if improved quality of life**
c. **Upgrade 1 level for confirmatory, adequately sized, phase 4 experience**

Final adjusted magnitude of clinical benefit grade

4	3	2	1