

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 >1 year

Grade 4

	Mark with ✓ if relevant
HR ≤0.70 <u>AND</u> gain ≥5 months	
Increase in 3-year survival alone ≥10%	

Grade 3

HR ≤0.70 <u>AND</u> gain 3 - 4.9 months	
Increase in 3-year survival alone 5 - <10%	

Grade 2

HR >0.70 - 0.75 <u>AND</u> gain 1.5 - 2.9 months	
Increase in 3-year survival alone 3 - <5%	

Grade 1

HR >0.75 <u>OR</u> gain <1.5 months	
Increase in 3-year survival alone <3%	

Preliminary magnitude of clinical benefit grade (highest grade scored)

4	3	2	1

Quality of Life/Grade 3-4 toxicities* assessment

Does secondary endpoint QoL show improvement?	
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.

Adjustments

Upgrade 1 level if improved QoL and/or less grade 3-4 toxicities impacting daily well-being are shown

Final adjusted magnitude of clinical benefit grade

5	4	3	2	1