

ESMO Magnitude of Clinical Benefit Scale v1.1

Form 1: for new approaches to adjuvant therapy or new potentially curative therapies

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

	Mark with X if relevant
Grade A	
>5% improvement of survival at ≥ 3 years follow-up	
Improvements in DFS alone (primary endpoint) (HR < 0.65) in studies without mature survival data	

Grade B

$\geq 3\%$ but $\leq 5\%$ improvement at ≥ 3 years follow-up	
Improvement in DFS alone (primary endpoint) (HR 0.65 - 0.8) without mature survival data	
Non inferior OS or DFS with reduced treatment toxicity or improved Quality of Life (with validated scales)	
Non inferior OS or DFS with reduced treatment cost as reported study outcome (with equivalent outcomes and risks)	

Grade C

$< 3\%$ improvement of survival at ≥ 3 years follow-up	
Improvement in DFS alone (primary endpoint) (HR > 0.8) in studies without mature survival data	
Improvements in pCR alone (primary endpoint) by $\geq 30\%$ relative AND $\geq 15\%$ absolute gain in studies without mature survival data	

Magnitude of clinical benefit grade (highest grade scored)

A	B	C