

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

For new approaches to adjuvant therapy or new potentially curative therapies

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

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 ≥3% BUT ≤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 QoL (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 ≥30% relative AND ≥15% absolute gain in studies without mature survival data

Mark with ✓ if relevant

Magnitude of clinical benefit grade (highest grade scored)	A	B	C
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Curative setting grading - A and B indicates a substantial magnitude of clinical benefit.