

ESMO-Magnitude of Clinical Benefit Scale for Haematological Malignancies

EVALUATION FORM 1A

For new potentially curative therapies

Name of stu	dy:						
Study medicine: Indicat First author: Year:		Indication:	on:				
		Year:	Journal:				
Name of eva	aluator:						
GRADE A	≥5% improvement of survival gain						
	Improvements in DFS alone (primary endpoint) HR ≤0.65 AND absolute gain ≥3% in studies without mature survival data						
GRADE B	≥3% - <5% improvement of overall survival gain						
	Improvements in DFS (primary endpoint) HR \leq 0.65 AND absolute gain \geq 1% - $<$ 3% in studies without mature survival data						
	Improvement in DFS (primary endpoint) HR >0.65 - 0.70 AND absolute gain ≥3% 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 gain						
	Improvement in DFS (primary endpoint) HR ≤0.65 AND absolute gain <1% in studies without mature* survival data						
	Improvement in DFS (primary endpoint) HR >0.65-0.75 AND absolute gain <3% in studies without mature* survival data						
	Improvement in DFS (primary endpoint) HR >0.75						
	Improvements in pCR alone (primary endpoint) by ≥30% relative AND ≥15% absolute gain in studies without mature* survival data						

*Note: For guidelines regarding maturity of survival data see instructions point 7 or adjustments below



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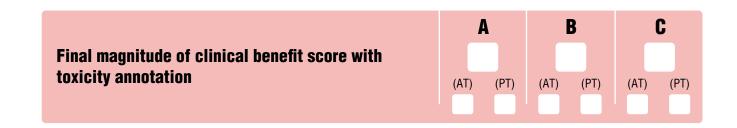
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Acute Transient Toxicity (AT)	
Is the new treatment associated with a rate of:	
Grade ≥3 adverse effects impacting well-being in >30% of patients	
Premature discontinuation of therapy due to adverse effects in >10% of patients	
Hospitalisation for adverse events in >10% of patients	
	Mark with √ if relevan
Persistent Toxicity (PT)	
Is the new treatment associated with:	
Chronic neuropathy in >20% of the patients*	
Other grade ≥3 chronic toxicity adversely impacting well-being in >20% of patients	
Curative therapies incorporating allogeneic bone marrow or stem cell transplant	
*Note: For guidelines regarding maturity of survival data see instructions point 7	Mark with √ if relevan

Adjustments

Downgrade 1 level if mature OS does not demonstrate significant benefit

Note: See instructions for use for guidelines regarding maturity of OS



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