ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale
for Haematological Malignancies

EVALUATION FORM 1A

For new potentially curative therapies

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

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 ≤0.65 AND absolute gain ≥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	☐

Mark with √ if relevant

Preliminary magnitude of clinical benefit score	**A** ☐	**B** ☐	**C** ☐

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

DFS, disease-free survival; HR, hazard ratio; OS, overall survival; pCR, pathologic complete response/remission.

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TOXICITY ANNOTATION

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 relevant

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 relevant

Adjustments

Downgrade 1 level if mature OS does not demonstrate significant benefit

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

Final magnitude of clinical benefit score with toxicity annotation	**A**		**B**		**C**	
	☐		☐		☐	
	(AT) ☐	(PT) ☐	(AT) ☐	(PT) ☐	(AT) ☐	(PT) ☐

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

AT, acute toxicity; OS, overall survival; PT, persistent toxicity.