

ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale
for Haematological Malignancies

EVALUATION FORM 1B

Single arm studies and de-escalation studies in the curative setting

Name of study:	<input type="text"/>		
Study medicine:	<input type="text"/>	Indication:	<input type="text"/>
First author:	<input type="text"/>	Year:	<input type="text"/>
		Journal:	<input type="text"/>
Name of evaluator:	<input type="text"/>		

- GRADE A** Multicentre trial with observed DFS or mature OS $\geq 2\%$ of the pre-specified target DFS or OS (at pre-specified relevant time point, derived from the standard of care)
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- GRADE B** Single-centre trial with observed DFS or mature OS $\geq 2\%$ of the pre-specified target DFS or OS (at pre-specified relevant time point, derived from the standard of care)
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- GRADE C** Trial with observed DFS or mature OS $> 2\%$ - $< 5\%$ of the pre-specified target DFS or OS (at pre-specified relevant time point, derived from the standard of care)

Mark with \surd if relevant

Preliminary magnitude of clinical benefit score	A	B	C
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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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 \surd 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 persistent toxicity see instructions point 7

Mark with \surd if relevant

	A	B	C
Final magnitude of clinical benefit score with toxicity annotation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	(AT) <input type="checkbox"/> (PT) <input type="checkbox"/>	(AT) <input type="checkbox"/> (PT) <input type="checkbox"/>	(AT) <input type="checkbox"/> (PT) <input type="checkbox"/>

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