ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale
for Haematological Malignancies

EVALUATION FORM 2C

For therapies that are not likely to be curative with primary endpoint other than OS or PFS or non-inferiority studies

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

Primary outcome is molecular response rate, response rate, toxicity or quality of life and non-inferiority studies

GRADE 4	Reduced toxicity* or improved QoL (using validated scale) with evidence for statistical non-inferiority or superiority in PFS/OS/CRR/MMR	☐
	Major molecular response rate (MR 4+) increased ≥20%	☐
GRADE 3	Improvement in some symptoms (using a validated scale) BUT without evidence of improved overall QoL	☐
	Major molecular response rate (MR 4+) increased 10 - <20%	☐
GRADE 2	RR is increased ≥20%	☐
	Major molecular response rate (MR 4+) increased ≥5 - <10%	☐
GRADE 1	RR is increased <20%	☐
	Major molecular response rate (MR 4+) increased <5%	☐

*This does not include alopecia, myelosuppression, but rather chronic nausea, diarrhoea, fatigue, etc.

Mark with √ if relevant

Preliminary magnitude of clinical benefit score	**4** ☐	**3** ☐	**2** ☐	**1** ☐

CRR, complete remission rate; MMR, major molecular response; MR, molecular response; OS, overall survival; PSF, progression-free survival; RR, response rate; QoL, Quality of Life.

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Incremental toxicity

Is the new treatment associated with an incremental rate of:

Fatal adverse events in ≥2% of patients	☐
Premature discontinuation of therapy in ≥10% of patients	☐
Hospitalisation for adverse events in ≥10% of patients	☐
Grade ≥3 mucositis in ≥10% of patients	☐
Grade ≥3 diarrhoea in ≥10% of patients	☐
Grade ≥3 fatigue in ≥10% of patients	☐
Grade ≥3 neurotoxicity in ≥10% of patients	☐
Other distressing toxicity grade ≥3 in ≥10% of patients	☐
Overall grade 3-4 toxicity impacting on daily well-being* or serious adverse events in ≥20% of patients	☐

Note: Incremental rate refers to the comparison versus standard therapy in the control arm

Mark with √ if relevant

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Quality of Life/Grade 3-4 toxicities assessment

Was QoL evaluated as secondary outcome? ☐

Does secondary endpoint QoL show improvement? ☐

Are there fewer grade 3-4 toxicities impacting on daily well-being?* ☐

*This does not include alopecia, myelosuppression, but rather chronic nausea, diarrhoea, fatigue, etc.

Mark with √ if relevant

Adjustments

01. When OS as secondary endpoint shows improvement, it will prevail and the scoring should be done according to form 2a

02. Upgrade 1 level if study with primary outcome of MR or RR demonstrates
a. Improved QoL OR
b. Fewer grade 3-4 toxicities that affect well-being of patients are demonstrated

03. Downgrade 1 level if the treatment has incremental toxicity

Final magnitude of clinical benefit score	**5** ☐	**4** ☐	**3** ☐	**2** ☐	**1** ☐

Non-curative setting grading 5 and 4 indicate a substantial magnitude of clinical benefit

MR, molecular response; OS, overall survival; RR, response rate; QoL, Quality of Life.