

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 3

For single-arm studies in “orphan diseases” and for diseases with “high unmet need” when primary outcome is PFS or ORR

| | | | |
|--------------------|----------------------|-------------|----------------------|
| 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 3 | PFS ≥ 6 months | <input type="radio"/> |
| | ORR (PR+CR) $\geq 60\%$ | <input type="radio"/> |
| | ORR (PR+CR) ≥ 20 - $<60\%$ <u>AND</u> DoR ≥ 9 months | <input type="radio"/> |
| GRADE 2 | PFS ≥ 3 - <6 months | <input type="radio"/> |
| | ORR (PR+CR) ≥ 40 - $<60\%$ | <input type="radio"/> |
| | ORR (PR+CR) ≥ 20 - $<40\%$ <u>AND</u> DoR ≥ 6 - <9 months | <input type="radio"/> |
| GRADE 1 | PFS 2- <3 months | <input type="radio"/> |
| | ORR(PR+CR) ≥ 20 - $<40\%$ <u>AND</u> DoR <6 months | <input type="radio"/> |
| | ORR (PR+CR) >10 - $<20\%$ <u>AND</u> DoR ≥ 6 months | <input type="radio"/> |

Mark with \checkmark if relevant

| | | | |
|---|--------------------------------------|--------------------------------------|--------------------------------------|
| Preliminary magnitude of clinical benefit grade (highest grade scored) | 3 <input type="checkbox"/> | 2 <input type="checkbox"/> | 1 <input type="checkbox"/> |
|---|--------------------------------------|--------------------------------------|--------------------------------------|

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

ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

Quality of life/Grade 3-4 toxicities* assessment

Was QoL evaluated as secondary outcome?

Does secondary endpoint QoL show improvement?

Are there $\geq 30\%$ grade 3-4 toxicities impacting on daily well-being?*

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

Mark with \checkmark if relevant

Adjustments

- A** Downgrade 1 level if there are $\geq 30\%$ grade 3-4 toxicities impacting on daily well-being*
- B** Upgrade 1 level if improved QoL
- C** Upgrade 1 level for confirmatory, adequately sized, phase 4 experience

| | 4 | 3 | 2 | 1 |
|---|--------------------------|--------------------------|--------------------------|--------------------------|
| Final adjusted magnitude of clinical benefit grade | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

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

QoL, quality of life