

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION FORM 2A

For therapies that are not likely to be curative with primary endpoint of OS

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

If median OS with the standard treatment >24 months

| GRADE 4 | HR ≤0.70 <u>AND</u> gain ≥9 months | |
|---------|---|------------|
| | Increase in 5 year survival alone ≥10% | \bigcirc |
| GRADE 3 | HR ≤0.70 <u>AND</u> gain ≥6-<9 months | \bigcirc |
| GRADE 2 | HR ≤0.70 <u>AND</u> gain ≥4-<6 months | |
| | HR >0.70-0.75 <u>AND</u> gain ≥4 months | \bigcirc |
| GRADE 1 | HR >0.75 <u>OR</u> gain <4 months | |

Mark with $\sqrt{}$ if relevant

| Preliminary magnitude of clinical benefit grade (highest grade scored) | 4 | 3 | 2 | 1 |
|---|---|---|---|---|
| | | | | |

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



Quality of life/Grade 3-4 toxicities* assessment

| Does secondary endpoint QoL show improvement? | | | |
|---|--------------------------|--|--|
| Are there statistically significantly less 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. Upgrade 1 level if improved QoL and/or less grade 3-4 toxicities impacting daily well-being are shown
- **02.** If there is a long term plateau in the survival curve, and OS advantage continues to be observed at 7 years, <u>also score</u> according to form 1 (treatments with curative potential) and present both scores i.e. A/4.



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OS, overall survival; QoL, quality of Life