

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE (V1.1)

ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

PROMOTING CLEAR AND EVIDENCE-BASED COMMUNICATION ABOUT THE BENEFIT OF CANCER TREATMENTS

Introduction

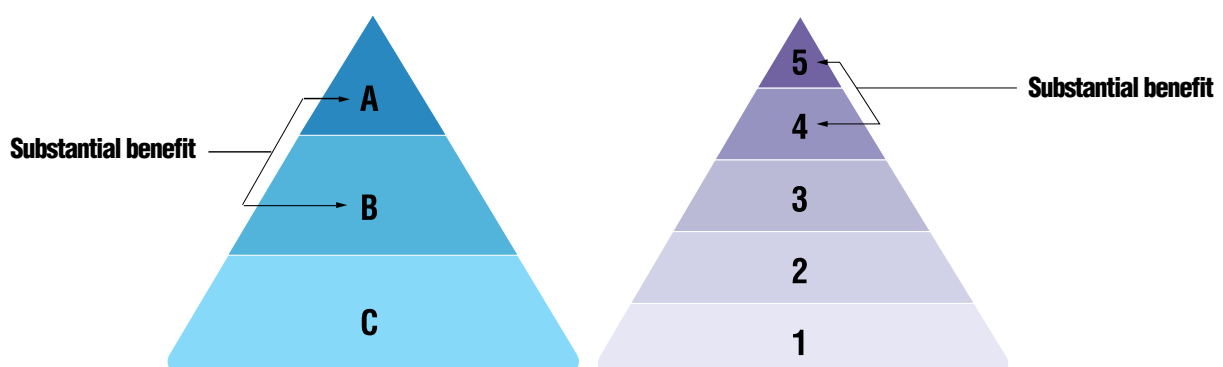
In 2015 the European Society for Medical Oncology (ESMO) launched the **ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS)** to facilitate improved decision-making regarding the value of anti-cancer therapies, promote the accessibility and reduce inequity of access to high value cancer treatments. Since value is based on considerations of the magnitude of clinical benefit as well as cost, and given the challenges to understanding the actual magnitude of the clinical benefit, the ESMO-MCBS was developed as a validated and reproducible scale that is applicable across the full range of solid tumours in oncology. It incorporates a structured, rational and valid approach to data interpretation and analysis that reduces the tendency to have judgements affected by bias or uninformed and/or idiosyncratic data interpretation that has been developed in accordance with the public policy standard of “accountability for reasonableness”. It is a dynamic tool and its criteria are revised on a regular basis. The ESMO-MCBS is an important first step to the critical public policy issue of value in cancer care, helping to frame the appropriate use of limited public and personal resources in the delivery of cancer care.

ESMO-MCBS: scoring criteria according to clinical settings

The scale considers overall survival, progression-free survival, disease free survival, hazard ratio, response rate, quality of life, prognosis of the condition and toxicity. There are 5 evaluation forms.

01. **Evaluation form 1: for new approaches to adjuvant therapy or new potentially curative therapies**
02. **Evaluation form 2a: for therapies that are not likely to be curative with primary endpoint of overall survival (OS) with separate sheets for:**
 - IF median OS with the standard treatment is ≤ 12 months
 - IF median OS with the standard treatment is >12 months, ≤ 24 months
 - IF median OS with the standard treatment is >24 months
03. **Evaluation form 2b: for therapies that are not likely to be curative with primary endpoint progression-free survival (PFS) with separate sheets for:**
 - IF median PFS with standard treatment is ≤ 6 months
 - IF median PFS with standard treatment is >6 months
04. **Evaluation form 2c: for therapies that are not likely to be curative with primary endpoint other than OS or PFS or equivalent (non-inferiority) studies.**
05. **Evaluation form 3: for single-arm studies in “orphan diseases” and for diseases with “high unmet need” when primary outcome is PFS or overall response rate (ORR).**

The highest grades of the **ESMO-MCBS** in the curative setting are A and B and in the non-curative setting 5 and 4, which indicate a substantial magnitude of clinical benefit.



What is the potential use and accessibility of the ESMO-MCBS?

This structured and disciplined approach to deriving estimates of clinically meaningful benefit from published data can be used in a range of settings, including:

- 1. Public policy applications** – Grading derived from the ESMO-MCBS provides a backbone for value evaluations of cancer medicines and can help public policy-makers in the advancement of ‘accountability for reasonableness’ in resource allocation deliberations.
- 2. Formulation of clinical guidelines** – For cancer therapies, the ESMO-MCBS scale provides a clear, well-structured and validated mechanism to indicate the magnitude of clinical benefit, in addition to the level of evidence, that can inform both national and international guidelines.
- 3. Clinical decision making** – The data enclosed in ESMO-MCBS scoring can help clinicians weigh the relative merits of competing relevant therapeutic options and may also be of benefit in explaining the relative merit of therapeutic options to patients and their families. This information may be especially helpful when treatments incorporate substantial out-of-pocket costs.
- 4. Editorial decisions and commentaries** – The ESMO-MCBS may be of use to editors, peer reviewers and commentators in considering the clinical significance of research findings from randomised clinical studies, cohort studies and meta-analyses with statistically significant positive findings.
- 5. Education** – The ESMO-MCBS is a powerful tool to teach a disciplined and validated approach to data interpretation. It is especially valuable for oncologists in training and for application in journal club discussion.

How is the ESMO-MCBS being used?

- It is incorporated in the ESMO Clinical Practice Guidelines and the Pan-Asian Adapted Guidelines, helping to provide patients with the best care options and setting the highest standards for cancer care.
- It has been acknowledged by the World Health Organisation as ‘a screening tool to identify cancer treatments that have potential therapeutic value that warrants full evaluation for the Essential Medicines List listing’¹.
- It is being used as part of HTA processes in a growing number of countries.
- It has been presented inside and outside Europe and in educational workshops for stakeholders, patient (advocates), pharma representatives and HTA bodies to increase knowledge sharing of the tool.
- It being used in oncology training programmes and journal club presentations, modelling a structured approach to data interpretation in the evaluation of clinical benefit.
- ESMO offers support to third parties wanting to use the scale.
- ESMO has developed a searchable portal and online tools to facilitate the use of the ESMO-MCBS.

The screenshot shows a search interface for the ESMO-MCBS. At the top, there are filter buttons for 'Agent', 'Tumour', and 'Score'. Below these are more specific filters: 'A (1)', 'Trastuzumab (1)', 'Tumour type', 'Tumour sub-type', and 'Tumour sub-group'. A 'reset selection' link is also present. The main part of the interface is a table with the following columns: Tested Agent, Combined Agent(s), Control Arm, Treatment Setting, Tumour Type, Tumour Sub-type, Tumour Sub-group, Tumour Stage, Score, Ref., and Score card. One result is shown for Trastuzumab, with a score of 'A'.

Tested Agent	Combined Agent(s)	Control Arm	Treatment Setting	Tumour Type	Tumour Sub-type	Tumour Sub-group	Tumour Stage	Score	Ref.	Score card
Trastuzumab		Chemotherapy	Adjuvant or neo-adjuvant HER2 positive tumours	Breast Cancer	Breast Cancer	HER2+	Early	A	🔗	➔

For more information visit our website <https://www.esmo.org/Guidelines/ESMO-MCBS> where you can find, among other things, the scale evaluation forms, the ESMO-MCBS scorecards, the presentations at the ESMO Congresses, and the articles published in ESMO Journals – or contact us at mchs@esmo.org.

¹ World Health Organisation. Executive Summary. The Selection and Use of Essential Medicines 2019. Report of the 22nd WHO Expert Committee on the Selection and Use of Essential Medicines, 1-5 April 2019.