

# EU HTA

## Procedural Insights

### Process Feed-Back Clinicians

**Prof. Dr. med. Bernhard Wörmann  
& Robin Doeswijk**

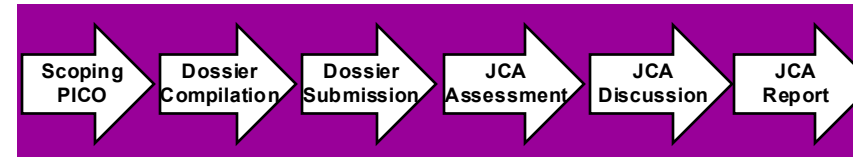
**EMA  
Approval**

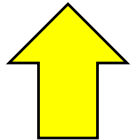
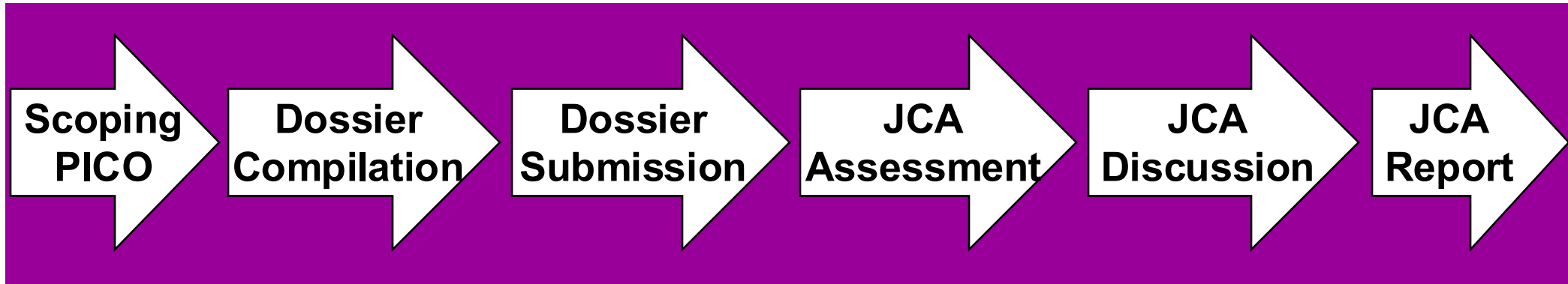


**Market  
Access**



**EMA  
Health Technology  
Assessment**





**Stakeholders**

**EU Scientific  
Medical  
Societies**



**Stakeholders**

**EU Scientific  
Medical  
Societies**



# Value Assessment of New Drugs

## PICO

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- Population
- Intervention
- Comparator
- Outcome

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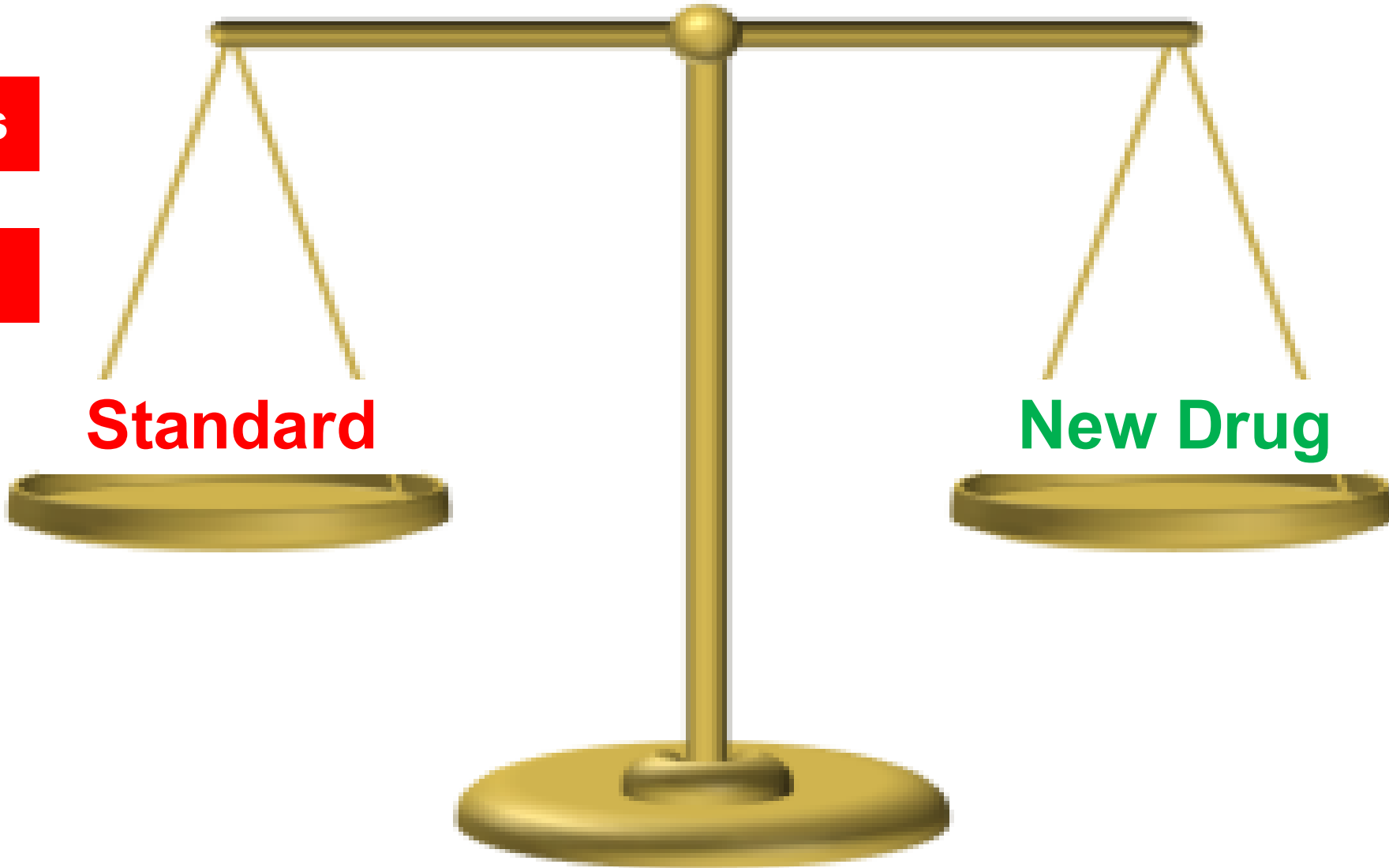
# Comparative Effectiveness

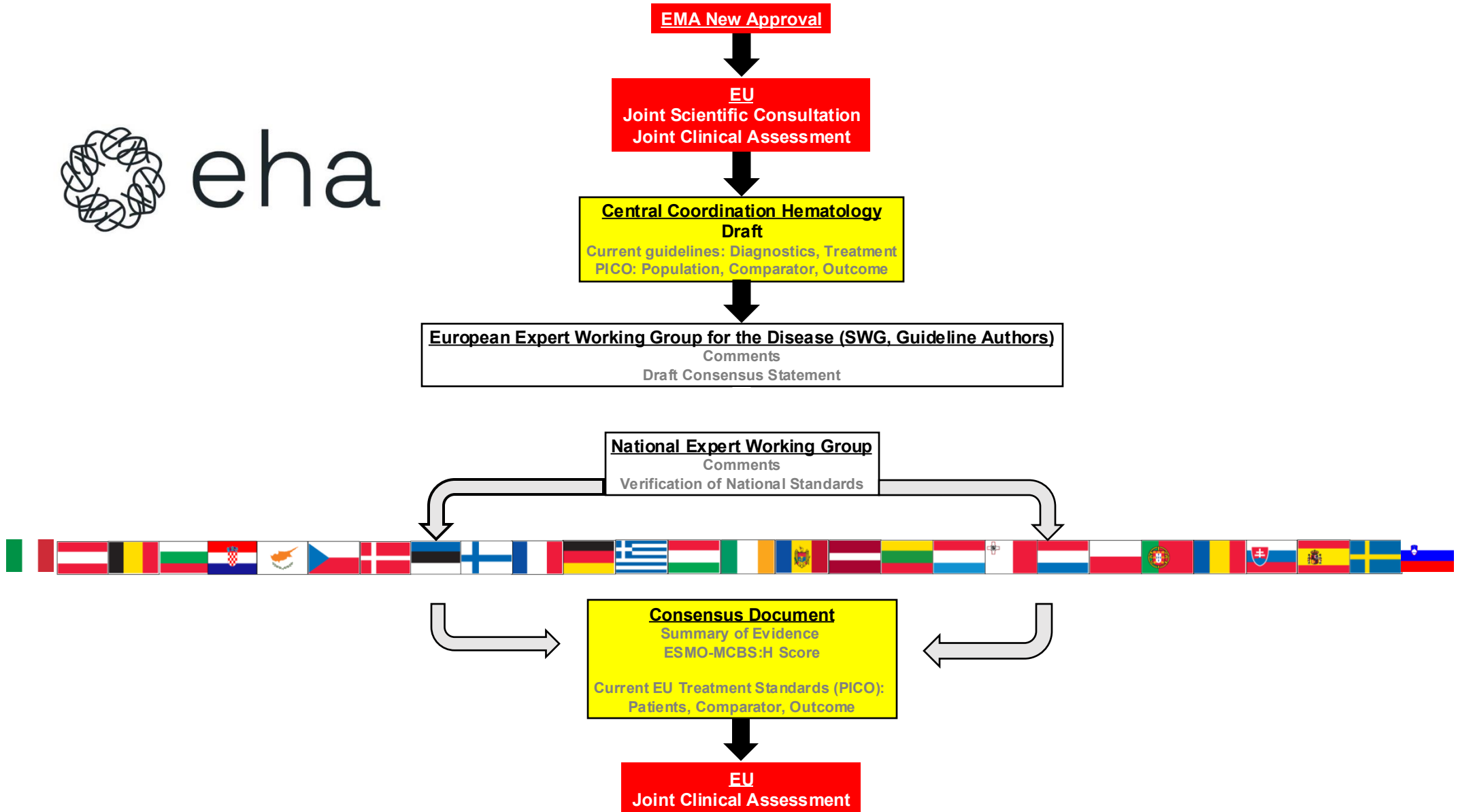
**Guidelines**

**Access**

**Standard**

**New Drug**





## Survey on Access to EMA approved Drugs 2015 - 2025

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all	142
Hematology, classical	20
Hemostaseology	18
Hematooncology	
Acute Leukemia	18
B-CLL	12
Lymphoid Neoplasia	
aggressive	18
indolent	17
other	5
Multiple Myeloma	20
Myeloid Neoplasia, excluding AML	14



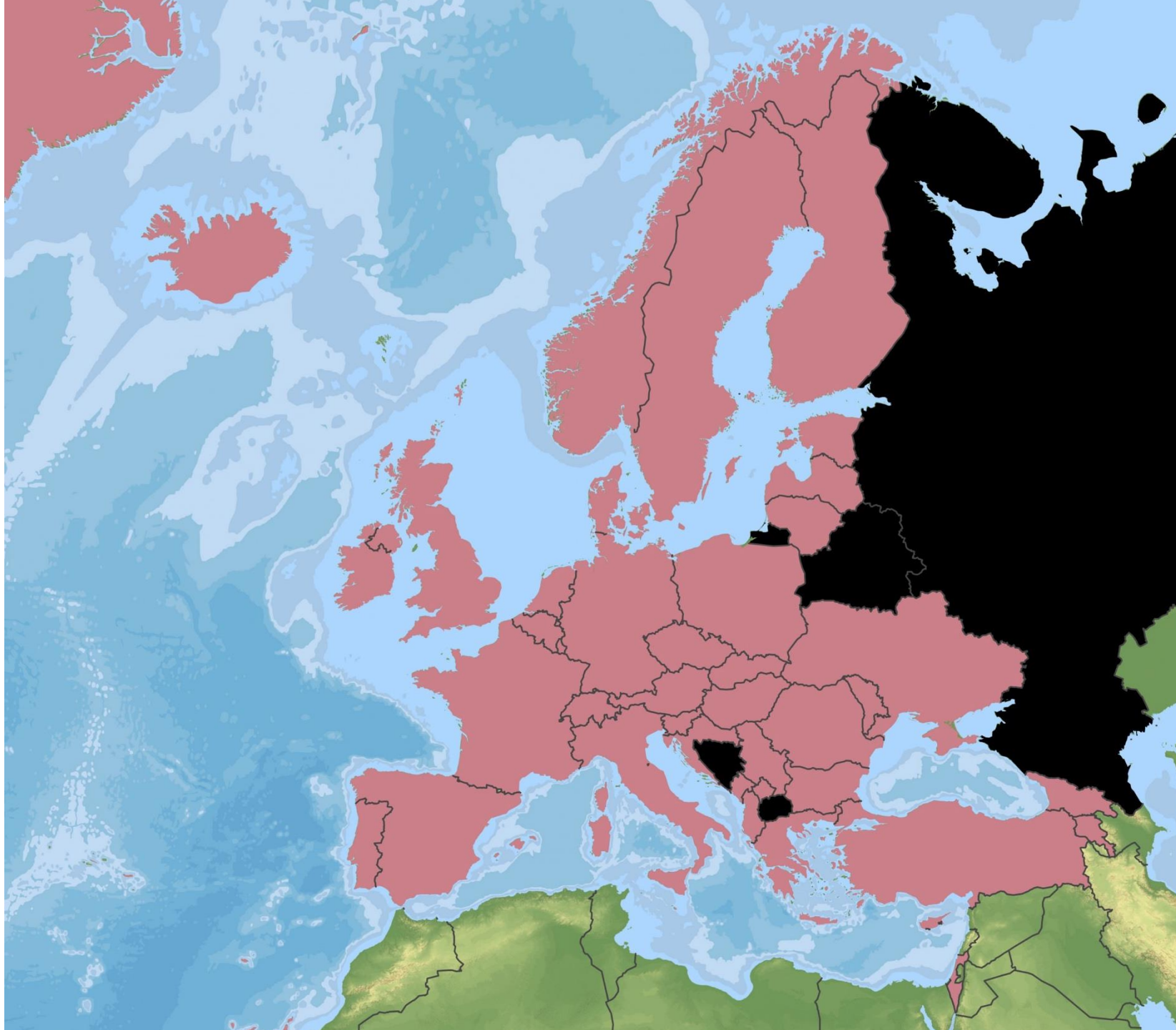
## Access to New Drugs Oct 29, 2025

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<b>Fully completed</b>	<b>38</b>	<b>EU</b>	<b>27</b>
<b>Partially completed</b>	<b>4</b>	<b>Non EU</b>	<b>15</b>
<b>No response</b>	<b>4</b>		

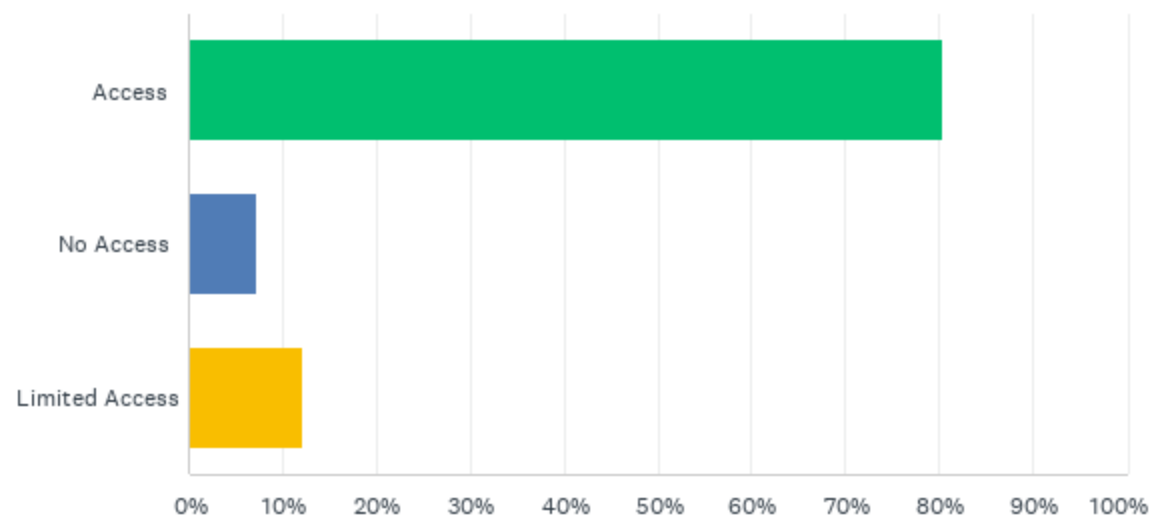
# Hematology

Access to new Drugs  
Status Oct 29, 2025



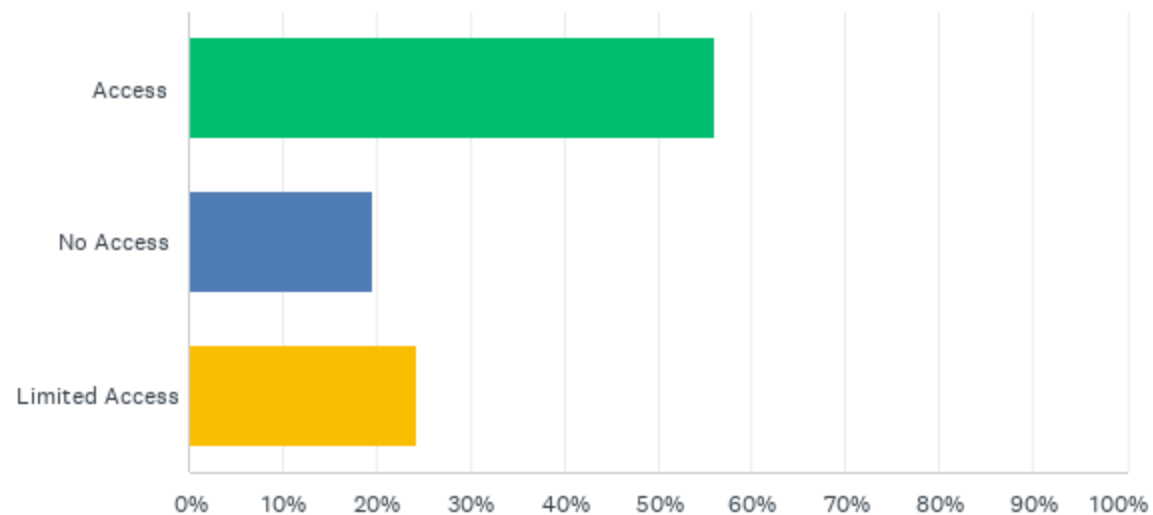
preliminary

## F8 Brentuximab Vedotin (Adcetris®), Hodgkin's Lymphoma, 2nd line after ASCT

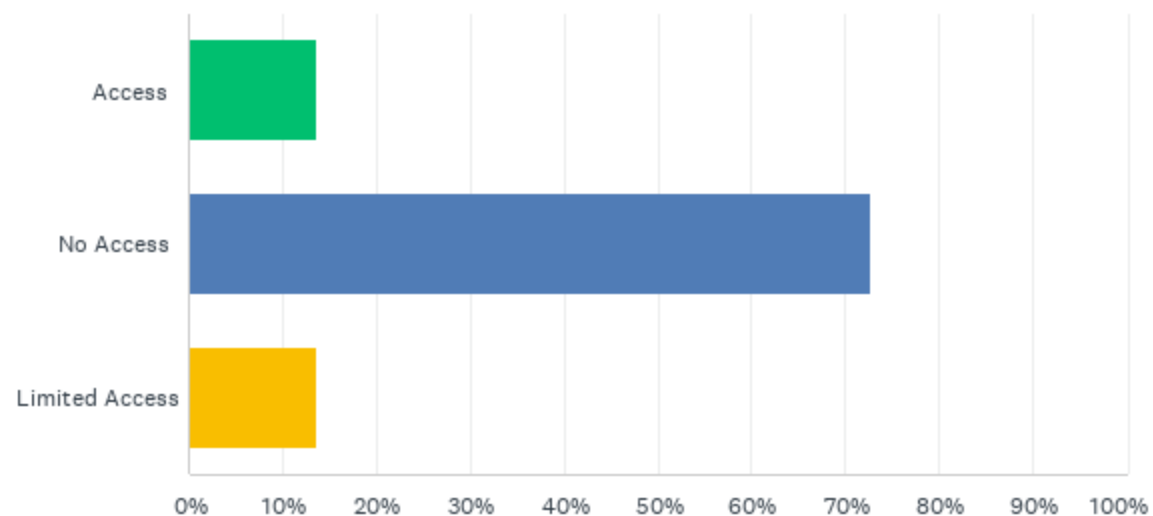


preliminary

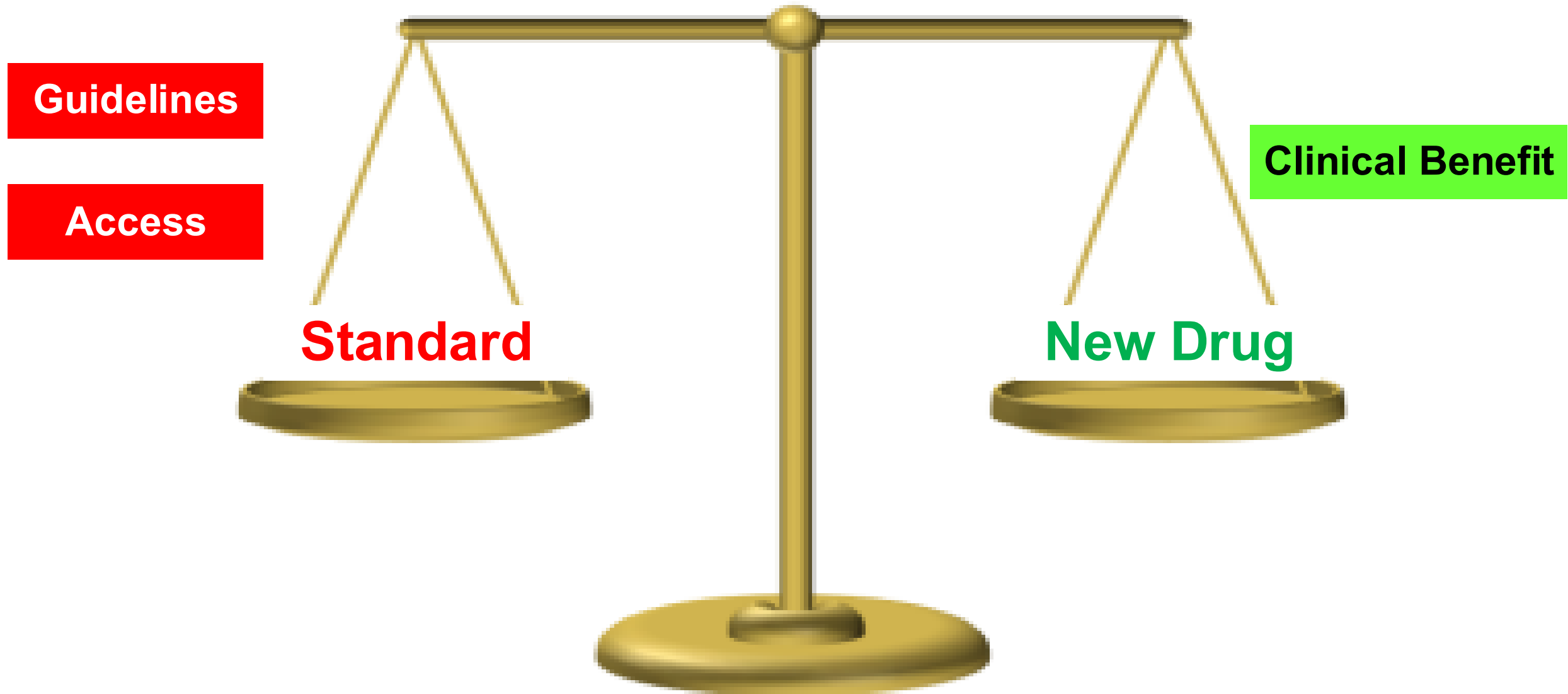
## F9 Daratumumab (Darzeva®), Multiple Myeloma, 1st line, + Bortezomib / Lenalidomide / Dexamethasone



## F16 Eptacog beta (activated) (Cevenfacta®), Hemophilia A and B, with inhibitors



# Comparative Effectiveness



## ESMO-MCBS:H Scorecards



# ESMO-MCBS:H

ESMO-Magnitude of Clinical Benefit Scale  
for Haematological Malignancies

## SCORECARDS

**The ESMO-MCBS:H Scorecards provides a centralised location of cancer medicines approved by the [European Medicines Agency](#) and the [US Food and Drug Administration](#) that have been scored and published by ESMO.**

ESMO-MCBS:H scores are based on peer reviewed clinical trial reports. They are generated using a validated standard methodology and are reviewed by a team of clinicians and statisticians before publication. ESMO-MCBS:H scores should be interpreted in the context of an evolving treatment landscape, in connection with clinical practice guidelines.

## Navigating the ESMO-MCBS:H Scorecards

This searchable portal allows [ESMO-MCBS:H Scorecards | ESMO](#)

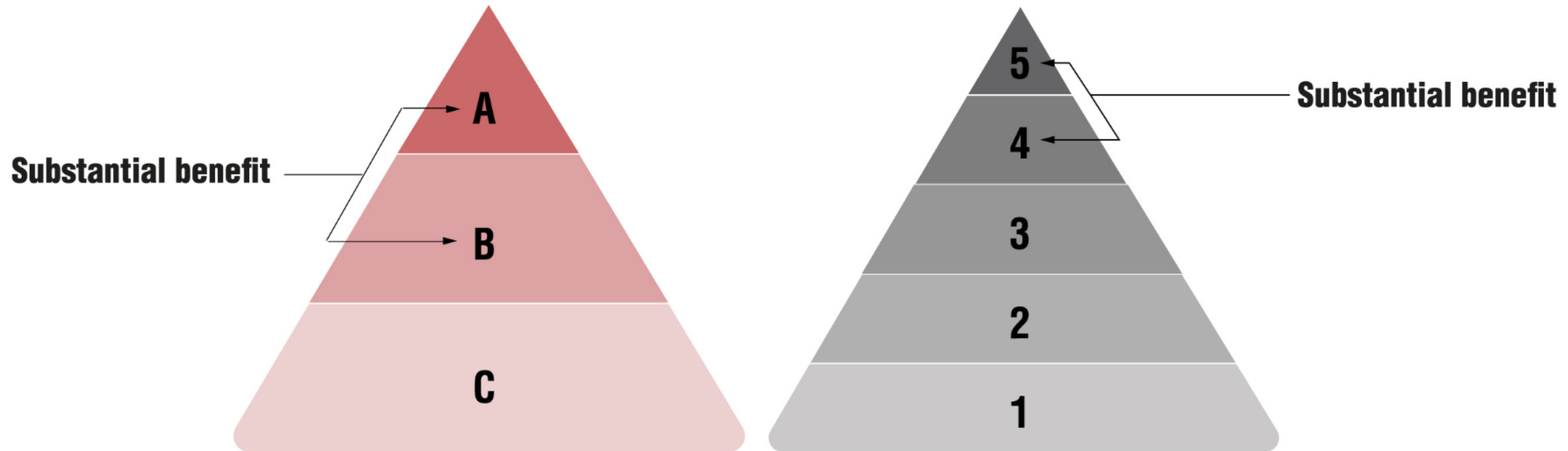
Each score is color-coded to reflect the clinical setting and type of outcome evaluated



# Clinical Benefit

## ESMO-MCBS score Magnitude of Clinical Benefit Scale MCBS:H

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







**Thank you for  
your attention**