Value-based frameworks in oncology
Clarity or confusion?

Prepared for:
European Statistical Meeting on Latest Trends in HTA

Prepared by:
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• Background – emerging trends in oncology HTA/market access

• What is value? The emergence of value-based decision making tools in oncology

• Compare and contrast – a critical review of the recently developed value frameworks

• Issues for implementation – what factors influence the outcomes in the frameworks?
Regulatory frameworks are accelerating the launch of new medicines

- Priority review
- Fast track
- Breakthrough therapy
- Accelerated approval

Some of these initiatives blur the lines between the traditional phases of clinical trials (e.g., single arm Phase 2 studies; combined Phase 1/2 trials)
Treatment landscapes are evolving very quickly

For example, in advanced melanoma, there were several treatments approved in a short time period – clinical guidelines struggle to keep up with the rate of change.
Progress has been seen in drug development

New classes of drugs have emerged that greatly improve outcomes for some patients; immuno-oncology (IO) agents are one such innovation.

Why are they different?

- IO drugs do not target the cancer directly, but instead target the body’s immune system to help it fight the cancer.
- Because IO agents give a long-lasting memory to the immune system, it can continually adapt to the cancer and provide a durable, long-term response to the cancer.
Views on treatment outcomes have changed

- In patients who respond to IO therapy, this could translate to long-term survival.
- IO agents have the ability to induce highly durable responses and long-term survival, resulting in a plateau in the tail of the Kaplan-Meier curves.
- Reliance on traditional survival metrics (e.g., hazard ratios) becomes problematic.
Healthcare pressures raise questions

- Who is the therapy for?
- How many people will need it?
- What are the current treatment options?
- Does it work better than what is prescribed now?
- How much (more) will it cost?
- Is it worth it?

There is increasing pressure to address some key issues.
Healthcare decisions are made by different groups

- **Healthcare system**: Efficient allocation of (scarce) resources
- **Clinician**: Disease knowledge & clinical experience
- **Patient**: Preferences & priorities
Choices are increasingly difficult to make

- Increasing number of choices available to clinicians
- But healthcare and pharmaceutical budgets are constrained.
- This had resulted in pressure on healthcare budgets and an increasing focus on value for money

The US healthcare market place has few tools to control cost effectively; in many European countries, health technology assessment (HTA) or pricing/reimbursement agencies fulfil this role, at least partly.
It is complex….

……but decision and choices need to be made…

……and decisions are being made in terms of “value”
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What is “value”?  

- I am selling a holiday in Greece for £500, including flights and accommodation.
- Would you like to buy it?
- Why?
Value can take many shapes and forms

“Value is an elusive target and there is no consensus about what dimensions should be taken into account”

Value

- Efficacy
- Innovation
- Impact on caregivers/family
- Safety
- Impact on HRQL
- Unmet need
- Convenience
- Cost/capacity
- Rarity of the condition

Neumann and Cohen, 2015
Value frameworks in oncology

May 2015

October 2015
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Value frameworks

- Healthcare system
- Clinician
- Patient

Assist clinicians in evaluating the most effective medicines for patients

Value frameworks

- Efficacy
- Safety
- Impact on HRQoL
- Impact on caregivers/family
- Convenience
- Cost/capacity
- Rarity of the condition
- Rarity of need
- Innovation
ESMO-MCBS: choice of evaluation form

1. For new approaches to adjuvant therapy or new potentially curative therapies

2a. For therapies that are not likely to be curative with primary endpoint of OS
   - 3 separate forms based on median OS for standard treatment

2b. For therapies that are not likely to be curative with primary endpoint PFS
   - 2 separate forms based on median PFS for standard treatment

2c. For therapies that are not likely to be curative with primary endpoint other than OS or PFS or equivalent (non-inferiority) studies

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

New for v1.1
ESMO-MCBS v1.1: scoring system

<table>
<thead>
<tr>
<th>Grade 4</th>
<th>Mark with X if relevant</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR ≤0.65 AND Gain ≥3 months</td>
<td></td>
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<tr>
<td>Increase in 2 year survival ≥10%</td>
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</table>

<table>
<thead>
<tr>
<th>Grade 3</th>
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<tbody>
<tr>
<td>HR ≤0.65 AND Gain ≥2.0, &lt;3 months</td>
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<thead>
<tr>
<th>Grade 2</th>
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<tbody>
<tr>
<td>HR ≤0.65 AND Gain ≥1.5, &lt;2.0 months</td>
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<tr>
<td>HR &gt;0.65-0.70 AND Gain ≥1.5 months</td>
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<table>
<thead>
<tr>
<th>Grade 1</th>
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<tbody>
<tr>
<td>HR &gt;0.70 OR Gain &lt;1.5 months</td>
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</tbody>
</table>

Quality of Life assessment / grade 3-4 toxicities assessment*

- Does secondary endpoint quality of life 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.

Adjustments

1. Upgrade 1 level if improved quality of life and/or less grade 3-4 toxicities impacting daily well-being are shown
2. If there is a long-term plateau in the survival curve, and OS advantage continues to be observed at 5 year, also score according to form 1 (treatments with curative potential) and present both scores i.e. A4

Preliminary magnitude of clinical benefit grade (highest grade scored)
Value frameworks

Healthcare system
Clinician
Patient

A tool for physicians to use with patients to discuss the relative value of new cancer therapies.

- Value
- Efficacy
- Safety
- Impact on HRQL
- Rarity of the condition
- Unmet need
- Cost/capacity
- Impact on caregiver/family
- Innovation
- Convenience

Schnipper et al., JCO Aug 2015; Schnipper et al., JCO, May 2016
Value frameworks

Healthcare system

Clinician

Patient

A tool to help determine appropriate prices for cancer drugs based on components of a drug’s value
Value frameworks

Support healthcare stakeholders and policy makers in discussions about the value of new drugs, providing the basis for price and coverage discussions.
Value frameworks

- Healthcare system
- Clinician
- Patient

Educate providers and payers; starting point for shared decision-making

https://www.nccn.org/evidenceblocks/
Value frameworks

Different target stakeholders, different approaches to value

- Healthcare system
- Clinician
- Patient
## Compare and contrast – elements of the framework

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<td>Contextual considerations</td>
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<td>Magnitude of clinical benefit (OS, PFS, response; plateau)</td>
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Adapted from Neumann and Cohen, 2015
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Considers relative improvement in efficacy endpoint

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Hierarchy/preference for efficacy endpoints

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Formal distinction between curative and non-curative treatments

Adapted from Neumann and Cohen, 2015
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Value frameworks – the details

Healthcare system
Clinician
Patient
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Implementation of VFs: Unituxin (dinutuximab)

FDA indication
- To treat pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy*

FDA evidence package
- Phase 3 trial of Unituxin combination therapy vs 13-cis-retinoic acid (RA) alone
- Event free survival as primary endpoint
- Early stopping of trial with median EFS for comparator of 1.9 years - not reached for Unituxin (HR = 0.57); analysis of OS conducted three years later showed HR 0.58 – median OS not reached in either arm

Value framework outcomes
- ASCO scores 0/130 (non-curative) or 28/100 (curative)
  - Non-curative: No median OS, PFS, or ORR (cannot score)
  - Curative: scores 3/5 clinical score (based on reported HR for OS)
- ESMO scores 0 (non-curative) or grade A (curative)
  - No curative: no score as primary endpoint is not OS or PFS and there is no improvement in ORR, HRQL, or toxicity
  - Curative: grade A, based on >5% increase in survival at 3 years

*In combination with GM-CSF, IL-2, and RA. Scored under ESMO-MCBS v1.0 and first iteration of ASCO VF
Implementation of VF: Keytruda (pembrolizumab)

FDA indication
• For the treatment of patients with unresectable or metastatic melanoma*

FDA evidence package
• Two Phase 3 trials vs active comparator (ipilimumab)
• One in first line (and one in melanoma refractory to ipilimumab and a BRAF inhibitor)
• PFS and OS as co-primary endpoints (median OS not reached for Keytruda although HR = 0.69, $P = 0.004$)

Value framework outcomes
• ASCO: score 22/130
  • PFS as primary endpoint: moderate 46% increase in median PFS (from 2.8 to 4.1 months) at 10 mg/kg Q3W (HR 0.58)
• ESMO: score 2/5
  • PFS gain also considered to be moderate and with HR of 0.58
    • Score of 3 for gain ≥1.5 months if comparator PFS ≤6 months
    • Score of 3 for gain ≥3 months if comparator PFS >6 months

*To include initial treatment. Scored under ESMO-MCBS v1.0 and first iteration of ASCO VF
Key issues for consideration

Different elements of value

• Different outcomes – value is not easy to define and quantify

Expressing preferences for different aspects of value

• Scoring
  • How are the thresholds between one score and another determined?

• Weighting
  • How are the relative weightings of the different components determined?

Transparency

Methodological basis
Statistical considerations

• Each ESMO-MCBS form is based on scores for exceeding thresholds of HR and survival gain.
• ESMO-MCBS uses the lower bound of the 95% CI of the HR to determine scores.
• This hypothetical situation can arise:

Product X
HR for OS 0.92
95% CI 0.59-0.99
0.59<0.65
score 3, 4 or 5

Product Y
HR for OS 0.82
95% CI 0.80-0.90
0.80>0.65
score 1, 2 or 3
ESMO-MCBS: implementation

• The ESMO-MCBS working group have identified 7 categories in which they believe the value framework is implemented.
• The information was based on:
  • interviews of people
  • publications
  • a survey of ESMO-members.

- ESMO organisation
- Academic groups
- Teaching
- Doctors in patient care
- Industry
- Organisations and countries using the scale as a policy tool
- Groups looking to application in other settings
ESMO-MCBS in HTA?

ESMO envisages that the scale will assist in the HTA process

Grading derived from the ESMO-MCBS provides a backbone for value evaluations for cancer medicines...While a high ESMO-MCBS score does not automatically imply high value (that depends on the price), the scale can be used to frame such considerations and can help public policymakers advance ‘accountability for reasonableness’ in resource allocation deliberations.

- Development of the scale did not involve any payer organisations (or patients).
- The scale was developed as a tool to derive clear and unbiased evaluation of the magnitude of clinical benefit based on published peer-reviewed data.
ESMO-MCBS in HTA?

**Australia**

ESMO-MCBS grading of cancer drugs are being provided by the Medical Oncology Group of Australia (MOGA) in their advice to Pharmaceutical Benefits Advisory Committee (PBAC).

**France**

The French HTA agency (HAS) provided feedback on ESMO-MCBS. They reviewed 77 trials using ESMO-MCBS v1.0 and compared it to the ASMR rating awarded by HAS:

- There were disparities between the ESMO-MCBS and the ASMR on the assessment of the clinical added value
- The ASMR appears to be more stringent in terms of:
  - level of evidence
  - comparator relevance
  - generalisability of results to real life situations
  - safety.

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**Table 1: Highest priority for PBS listing**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Comparator</th>
<th>Pivotal Trial</th>
<th>Disease/Indication</th>
<th>Survival benefit</th>
<th>Less toxic</th>
<th>ESMO-MCBS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nivolumab</td>
<td>Everolimus</td>
<td>CHECKMATE-251</td>
<td>Renal cell carcinoma (clear cell)</td>
<td>Yes</td>
<td>Yes</td>
<td>5</td>
</tr>
<tr>
<td>Pembrolizumab</td>
<td>Platinum-based chemotherapy</td>
<td>KEYNOTE-024</td>
<td>Non-small cell lung cancer (PD-L1 ≥50%)</td>
<td>Yes</td>
<td>Yes</td>
<td>5</td>
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Mathilde Grande et al., 2017, ESMO presentation, How to assess a cancer therapy?
ESMO-MCBS – out of context?

A study published in The BMJ this week shows how most new cancer drugs are failing to deliver any clinically meaningful benefit. It’s time for Europe to raise the evidence bar before market approval.

Of 23 indications associated with a survival benefit that could be scored with the ESMO-MCBS tool, the benefit was judged to be clinically meaningful in less than half (11/23, 48%).

But when interpreting the findings, we should consider:

• Is the measure fit for purpose?
• Which perspective of value is incorporated in measure?
Some other considerations

• The simplicity of single scores can make value frameworks an attractive tool for decision-makers.

• However, variation in the domains included, the scoring methodology, and the weights used to aggregate to a single overall score leads to large variations in the assessment of relative value across value frameworks.

• Understanding the underlying methodology of each value framework is important for interpreting their outputs and applying them appropriately.

• This can be hindered by lack of transparency on some key aspects, including scoring and weighting and the underlying perspective the value framework represents.
It is complex

Value is being assessed in different ways and to a different level of complexity by each of these agencies.
Conclusion: the fifth hurdle?

Clarity?
• Works in progress and likely to remain
• Potential to provide context to understand value for multiple stakeholders
• Making decision-making more transparent

Confusion?
• Next iterations need to address existing methodological concerns
• Potential disconnect in incentives with needs of regulatory and HTA bodies
• Concern that the frameworks could be inappropriately used in decision-making

Value frameworks are a welcome development but further evolution will be necessary to produce more transparent and robust tools for decision-makers.
Questions
For more information, please contact prma consulting using the details below or visit our website.

www.prmaconsulting.com