Evaluation of Current Value Models

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What is “Value”?

$$\text{Value} = \frac{\text{Net Outcomes: beneficial-detrimental}}{\text{Financial Cost}}$$

Net Outcomes

- Our goal is Health, not Healthcare
- Benchmarks are outcomes not process
- Our goal is optimizing cancer patients health
  - During the delivery of care
  - Post intervention

ICHOM International Consortium for Health Outcomes Measurement

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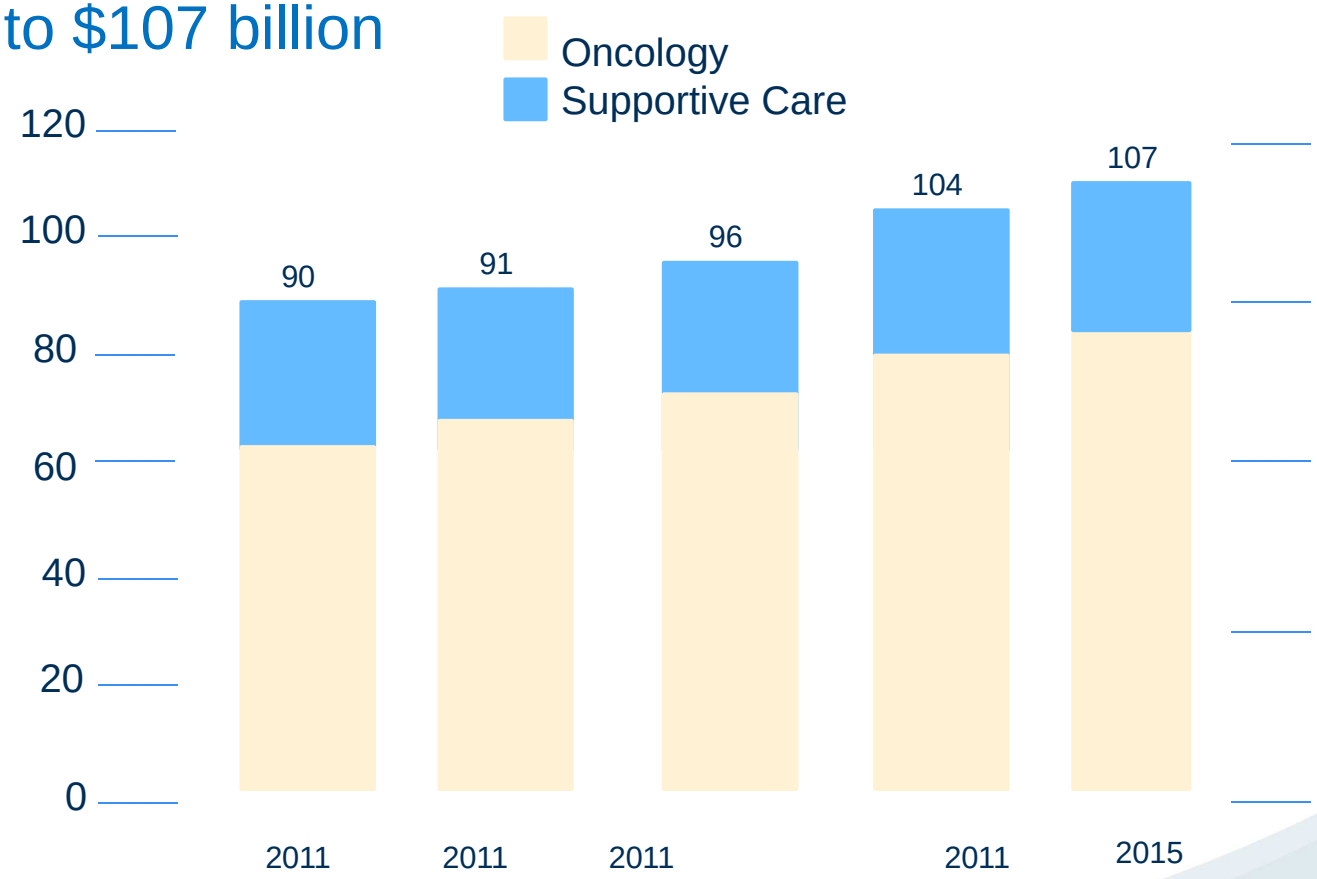
Global costs of oncology therapeutics and supportive care medicines increased 11.5% in 2015 to $107 billion



Source: IMS Global Oncology Trend Report: A Review of 2015 and Outlook to 2020

Determining Cost

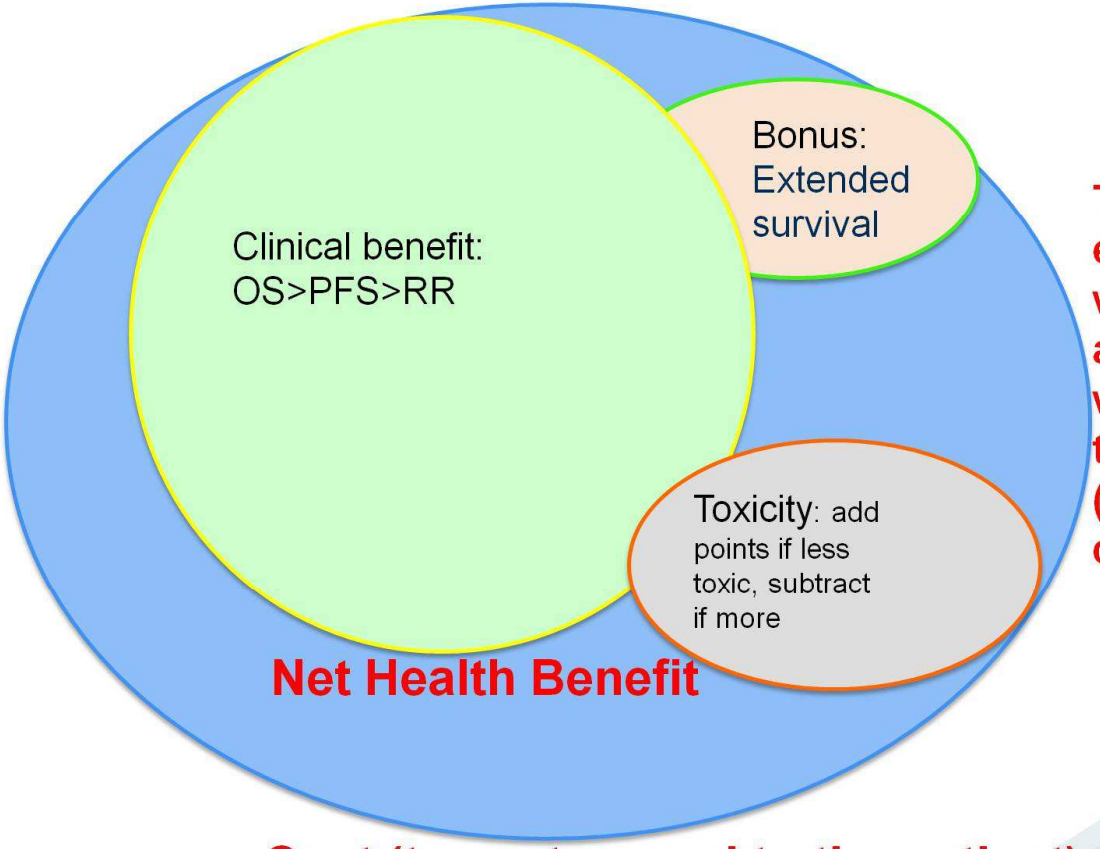
- CMS ASP: drug distributor cost
- Health system/practice: acquisition cost
- Patient: co-pay, co-insurance, deductible
- Employers: Insurance
- Life Sciences company: R&D
- By disease indication?

There are Multiple Value Frameworks

- ASCO's Value Framework
- ESMO's Magnitude of Clinical Benefit Scale (MCBS)
- The NCCN Evidence Blocks™
- Memorial Sloan Kettering Cancer Center's Drug Abacus Tool
- ICER's Value Assessment Framework

Net Health Benefit and Cost: the ASCO Framework

Comparison in a trial: test vs standard



The weight of each domain will be adjustable when using the tool (App) we will design

Cost (to system and to the patient)

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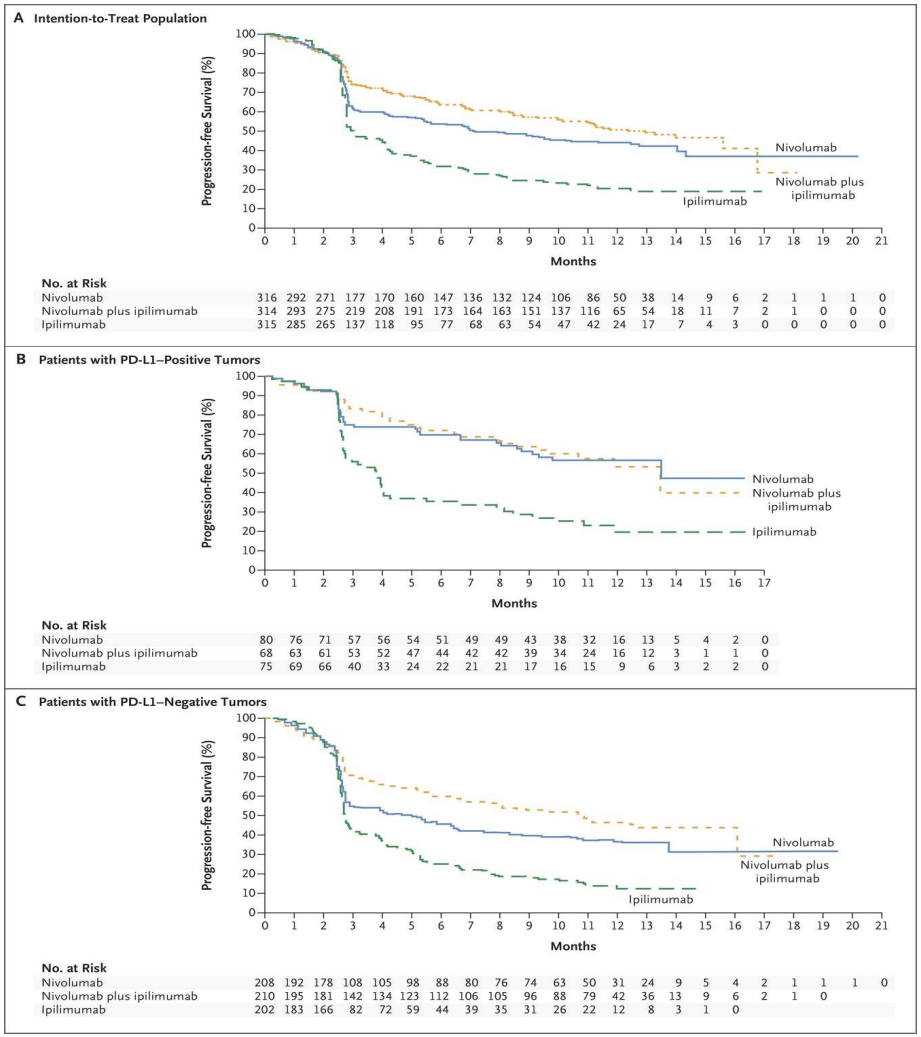
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Combined Nivolumab and Ipilimumab or Monotherapy in Untreated Melanoma

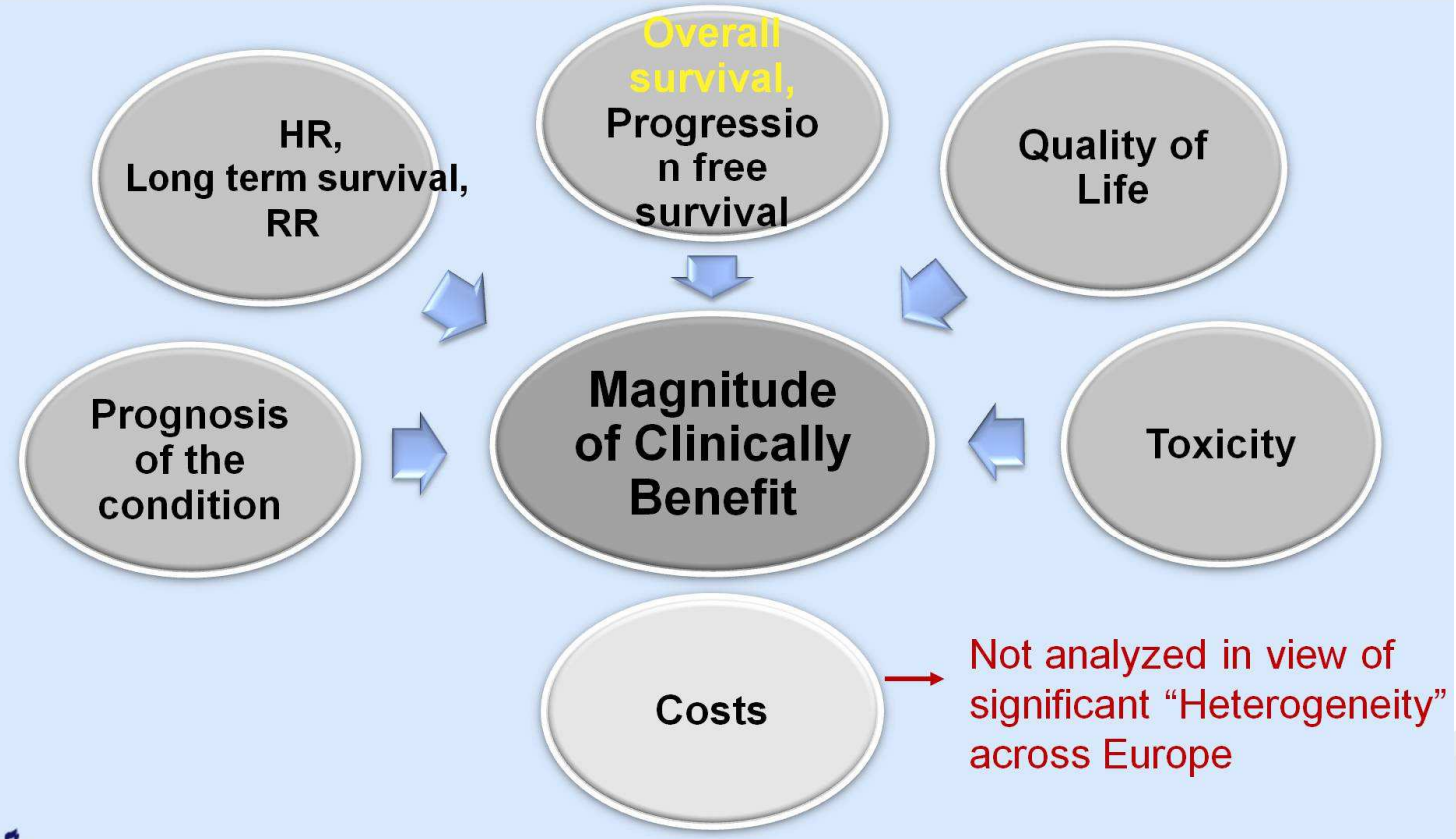
J. Larkin, V. Chiarion-Sileni, R. Gonzalez, J.J. Grob, C.L. Cowey, C.D. Lao, D. Schadendorf, R. Dummer, M. Smylie, P. Rutkowski, P.F. Ferrucci, A. Hill, J. Wagstaff, M.S. Carlino, J.B. Haanen, M. Maio, I. Marquez-Rodas, G.A. McArthur, P.A. Ascierto, G.V. Long, M.K. Callahan, M.A. Postow, K. Grossmann, M. Sznol, B. Dreno, L. Bastholt, A. Yang, L.M. Rollin, C. Horak, F.S. Hodi, and J.D. Wolchok



Nivolumab + Ipilimumab versus Ipilimumab

Score	All Patients	PD-L1 Negative
Clinical Benefit	26	41.6
Toxicity	11.6	11.6
Net Health Benefit	14.4	30

Factors taken into account for ESMO-MCBS



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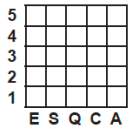
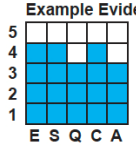
NCCN EVIDENCE BLOCKS CATEGORIES AND DEFINITIONS



E = Efficacy of Regimen/Agent
S = Safety of Regimen/Agent
Q = Quality of Evidence
C = Consistency of Evidence
A = Affordability of Regimen/Agent

Example Evidence Block



E = 4
S = 4
Q = 3
C = 4
A = 3

Efficacy of Regimen/Agent

5	**Highly effective:** Often provides long-term survival advantage or has curative potential
4	**Very effective:** Sometimes provides long-term survival advantage or has curative potential
3	**Moderately effective:** Modest, no, or unknown impact on survival but often provides control of disease
2	**Minimally effective:** Modest, no, or unknown impact on survival and sometimes provides control of disease
1	**Palliative:** Provides symptomatic benefit only

Safety of Regimen/Agent

5	**Usually no meaningful toxicity:** Uncommon or minimal side effects. No interference with activities of daily living (ADLs)
4	**Occasionally toxic:** Rare significant toxicities or low-grade toxicities only. Little interference with ADLs
3	**Mildly toxic:** Mild toxicity that interferes with ADLs is common
2	**Moderately toxic:** Significant toxicities often occur; life threatening/fatal toxicity is uncommon. Interference with ADLs is usual
1	**Highly toxic:** Usually severe, significant toxicities or life threatening/fatal toxicity often observed. Interference with ADLs is usual and/or severe

Note: For significant chronic or long-term toxicities, score decreased by 1

Quality of Evidence

5	**High quality:** Multiple well-designed randomized trials and/or meta-analyses
4	**Good quality:** Several well-designed randomized trials
3	**Average quality:** Low quality randomized trials or well-designed non-randomized trials
2	**Low quality:** Case reports or clinical experience only
1	**Poor quality:** Little or no evidence

Consistency of Evidence

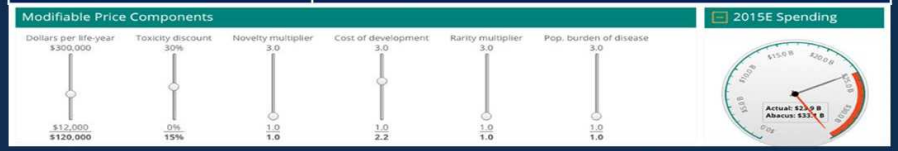
5	**Highly consistent:** Multiple trials with similar outcomes
4	**Mainly consistent:** Multiple trials with some variability in outcome
3	**May be consistent:** Few trials or only trials with few patients; lower quality trials whether randomized or not
2	**Inconsistent:** Meaningful differences in direction of outcome between quality trials
1	**Anecdotal evidence only:** Evidence in humans based upon anecdotal experience

Affordability of Regimen/Agent (includes drug cost, supportive care, infusions, toxicity monitoring, management of toxicity)

5	**Very inexpensive**
4	**Inexpensive**
3	**Moderately expensive**
2	**Expensive**
1	**Very expensive**

ABACUS Value Framework

The Core Question	What is the just price for a cancer drug?
Factors Considered	• Efficacy • Cost • Toxicity • Treatment Novelty • Costs of development • Rarity of disease • Population burden of condition
What evidence?	Phase II and III Drug Trials
Who judges?	Each user can customize own inputs
Whose perspective?	Manufacturer setting launch price, health insurer, concerned citizen



Daratumumab for Myeloma

✓✓ ✓ **High efficacy**
✓✓✓ **Novel mechanism**

What is a fair launch price?

Can the >$10,000 per month be justified?

PRESENTED AT: ASCO ANNUAL MEETING '16

Peter Bach MD see http://www.drugabacus.org/

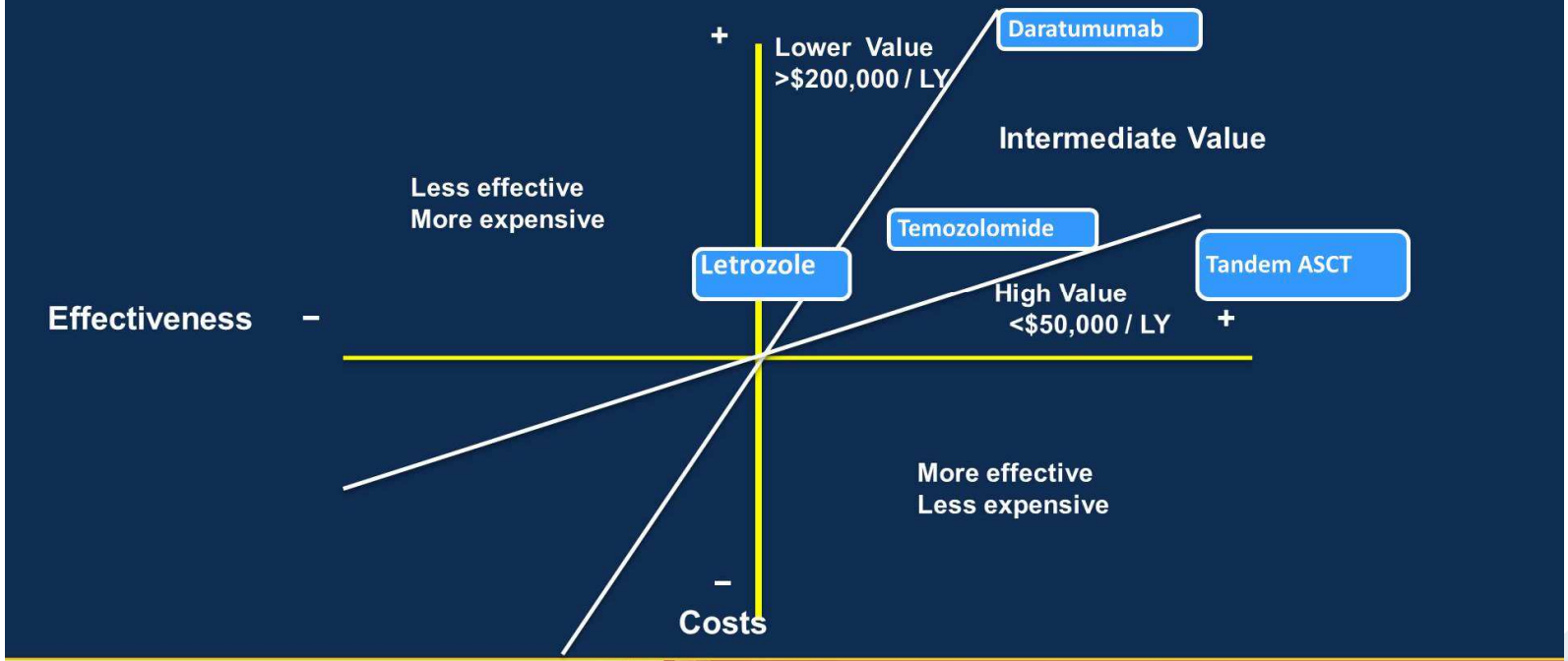
ICER Value Framework

(Institute for Clinical and Economic Review)

$$\text{Incremental Cost Effectiveness Ratio} = \frac{\text{Cost}_{new} - \text{Cost}_{standard}}{\text{Effectiveness}_{new} - \text{Effectiveness}_{standard}}$$

- Very few clinical trials include prospective CEA
- Post-hoc analyses miss important cost drivers

ICER Framework:
Cost Effectiveness Modeling and "Expert" Input



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Estimates based on regimen specific dosing
CMS and redbook drug prices

How they split: Value

Outcomes

- ASCO Value Framework
- ESMO MCBS
- NCCN Evidence Blocks
- ICER

Cost

- NCCN Evidence Blocks
- MSKCC Abacus
- ICER

How they split: Perspectives

Societal

- ESMO MCBS
- MSKCC Abacus
- ICER

Patient

- ASCO Value Framework
- ESMO MCBS
- NCCN Evidence Blocks


uicc
global cancer control
FIGHTING CANCER TOGETHER
Addressing the Needs of Cancer Patients Worldwide in the WHO Model Essential Medicines List
"We unite the cancer community to reduce the global cancer burden, to promote greater equity, and to integrate cancer control into the world health and development agenda."

ASCO

WHO Essential Medicines List Framework

Four Main Dimensions with Three Levels Each:

- **Efficacy and Safety of Therapy**
  - Cure, Near Cure, Prolongation of Survival/Palliation
  - Adequate Safety
- **Burden of Disease**
  - Low, Mid and High Incidence
- **Cost Effectiveness of Drug/Regimen**
  - Highly Cost Effective, Cost Effective and Not Cost Effective
- **Resource Requirements for Drug Use**
  - Low, Middle and High requirement levels

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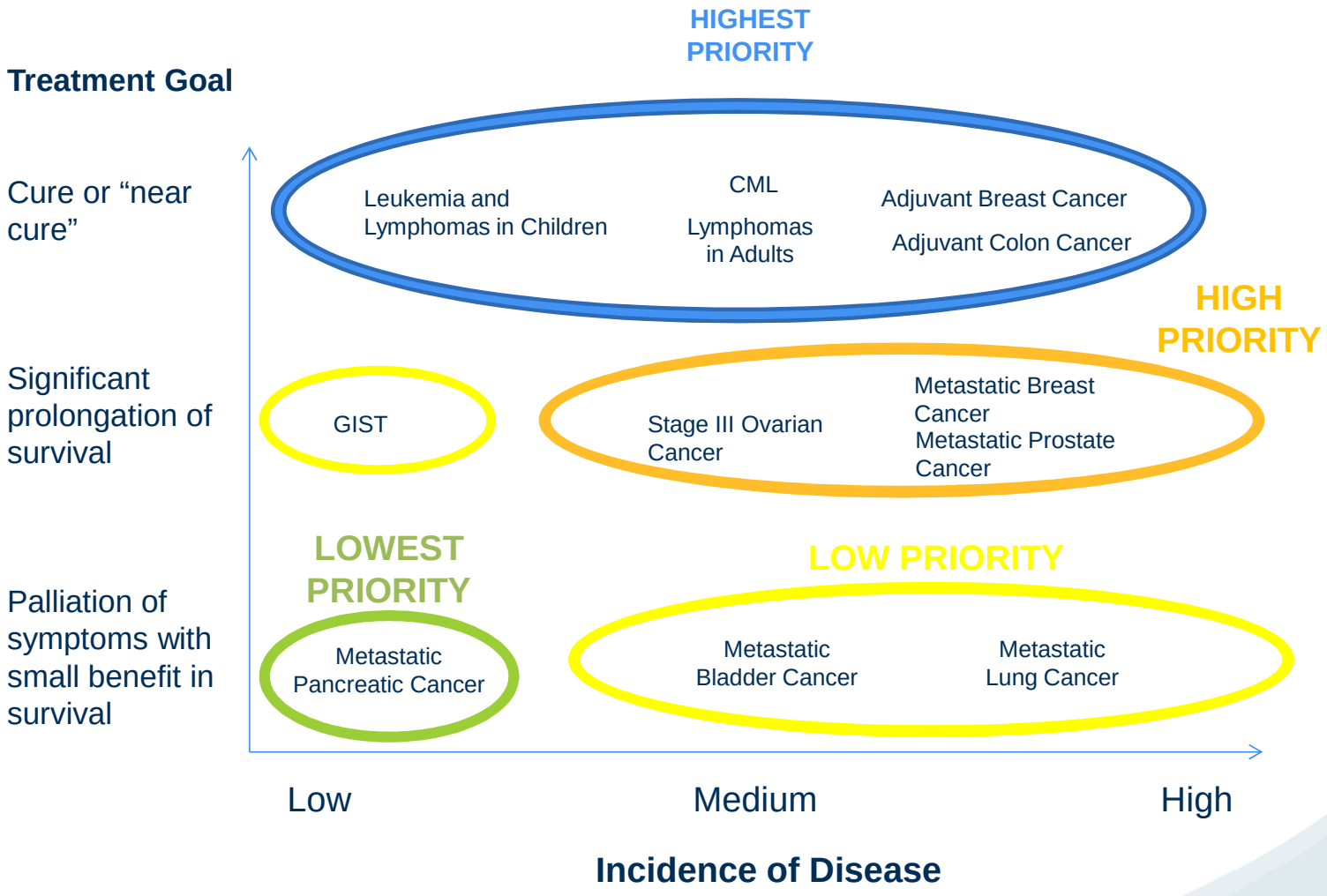

Low priority can become High Priority if Highly Cost Effective

FOR EACH CATEGORY

Highly Cost Effective
[Cost/QALY equal or less than GDP/capita]

Cost Effective
[Cost/QALY up to 3x GDP/Capita]

Not Cost Effective
[Cost/QALY > 3x GDP/Capita]

1. Different levels for low income, low middle income and high middle income countries.
2. Health systems should see the CE evaluation as a tool to discuss/negotiate prices of priority medications not as a rigid recommendation.

Conclusions

- Multiple Models
- Address different components of Value
- Speak to different audiences
- They serve to advance discussions
- Solutions are societal